



INSTITUTO UNIVERSITÁRIO EGAS MONIZ

MESTRADO INTEGRADO EM CIÊNCIAS FARMACÊUTICAS

**AVAILABILITY, IMPLEMENTATION AND REMUNERATION OF
PHARMACIST-LED COGNITIVE SERVICES IN EUROPE**

Trabalho submetido por
MARIA INÊS BRANCO GONÇALVES SOARES
para a obtenção do grau de Mestre em Ciências Farmacêuticas

junho de 2018



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Trabalho orientado por
Prof. Doutora Filipa Alves da Costa

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junho de 2018

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Resumo

Introdução: Consideram-se Serviços Farmacêuticos (SF) como atividades prestadas em farmácias para melhorar o nível de saúde da comunidade local. A informação sobre o nível de implementação e os modelos de remuneração destes SF está ausente ou superficialmente descrita na literatura.

Objetivos: Rever a implementação dos SF em cuidados primários na Europa e explorar os modelos de remuneração associados.

Metodologia: Foram abordados representantes de 44 regiões/países Europeus através de um estudo transversal, recorrendo a um inquérito *online* (de Novembro de 2016 a Outubro de 2017). Para um conjunto de 22 SF, foram questionados sobre a disponibilidade, o nível de implementação e a remuneração. Usaram-se três representantes por país: organizações profissionais, meio académico e farmácia comunitária, para garantir a triangulação dos dados. Recorreu-se a uma técnica de consenso para validação dos dados. A análise foi realizada em Excel, 2010. O projeto foi aprovado pela Comissão de Ética da Egas Moniz (Proc. 515)

Resultados: Obtiveram-se respostas de 34 países/regiões Europeus (79%). Os SF mais disponíveis nas regiões/países da Europa foram: prestação de informação sobre medicamentos (94.1%), substituição por genéricos (85.3%), revisão da medicação (79.4%), prestação de contraceção oral de emergência (70.6%) e testes *point-of-care* (67.7%). Os SF prestados num elevado nível de implementação são: revisão da medicação, apoio na adesão à terapêutica, renovação da prescrição, terapêutica de substituição opióide e programas de medicina do viajante. Foram descritos modelos de remuneração por cerca de metade dos participantes, sendo predominante o modelo *fee-for-service*, e menos frequentes os modelos *pay-for-performance* ou *mixed models*.

Conclusão: O número de SF prestados em farmácia comunitária na Europa tem vindo a aumentar e a ser diversificado. A elevada amplitude nos níveis de implementação descritos sugere a inexistência ou limitação de fontes oficiais de monitorização. Os modelos de remuneração são cada vez mais comuns, ainda que não tenha sido encontrado nenhum padrão entre a disponibilidade do serviço e a remuneração.

Palavras-chave: Serviços farmacêuticos; Cuidados Farmacêuticos; Europa; Remuneração

Abstract

Introduction: Pharmacist-led cognitive services (PLCS) comprise a range of activities provided by pharmacists to the local community focusing on patient-centredness. However, the implementation level and remuneration models of PLCS are either absent or superficially described in the literature.

Objectives: To review the implementation of PLCS in primary care across Europe and to explore the associated third-party paid remuneration models.

Methodology: A cross-sectional study was conducted using an online survey sent to representatives of 44 European countries/regions (between November 2016 and October 2017). The survey listed 22 PLCS and asked respondents to report the availability of the service, the rate of implementation and the existence of remuneration. Data triangulation was sought using three representatives per country/region, representing backgrounds of community pharmacy, pharmacy practice research and health policy. Subsequent consensus was sought. Data was analysed using excel, 2010. The project was approved by the Research Ethics Committee of Egas Moniz (Proc. 515)

Results: Data from 34 different countries/regions across Europe (79%) were obtained. Provision of medicines' information (94.1%), generic substitution (85.3%), medication review (79.4%), provision of emergency oral contraception (70.6%) and point-of-care testing (67.7%) were the most frequently reported services. The highest implementation rates were found for medication review, adherence support and monitoring, prescription renewal, opioid substitution and travel medicine. Some type of remuneration model was mentioned in half of the participating countries/regions, predominantly based on a fee-for-service, with less frequent reports of pay-for-performance or mixed models.

Conclusion: The availability of PLCS is increasing and varying in scope across Europe. The wide range of reported implementation levels suggests there is lack or limited public information for monitoring service implementation. Remuneration of PLCS is spreading, although no clear patterns were found between service provision and payment.

Keywords: Community pharmacy services; Pharmaceutical Care; Europe; Remuneration

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List of Abbreviations

ART - Antiretroviral therapy
COPD - Chronic Obstructive Pulmonary Disease
CPS - Cognitive Pharmaceutical Services
ESCP - European Society Clinical Pharmacy
EU - European Union
FFS - Fee-for-service
FIP - International Pharmaceutical Federation
FISpH - Framework for the Implementation of Services in Pharmacy
GP - General Practitioner
GPP - Good Pharmacy Practice
HCB - Hepatitis B virus
HCP - Health Care Professionals
HCV - Hepatitis C virus
HIV - Human Immunodeficiency virus
I-MUR - Italian Medicines use Review
INR – International Normalized Ratio
MeSH - Medical Subject Headings
MH - Ministry of Health
MM - Mixed Models
MR - Medication Review
MURs - Medicines Use Reviews
NAP - National Association of Pharmacies
NDPs - Non-dispensing pharmacists
NHS - National Health Service
NMS - New Medicine Service
OECD - Organisation for Economic Co-operation and Development
OOP - Out-of-Pocket
P4P - Pay-for-performance
PCNE - Pharmaceutical Care Network Europe
PGEU - Pharmaceutical Group of the European Union
PLCS - Pharmacist-led Cognitive Services
PPS - Portuguese Pharmaceutical Society
PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement
QALY - Quality-adjusted life-years
SFT - Seguimiento Farmacoterapéutico
UK - United Kingdom
WHO - World Health Organization

Chapter 1 – Introduction

1.1 – Background

Pharmacists, as part of the primary care team, work closely with the local community and their interventions have an undisputed positive impact on public health (Félix *et al.*, 2017; Hazen *et al.*, 2018).

Pharmacist-led cognitive services (PLCS) act as a pillar to develop new solutions for the delivery of better healthcare. The ultimate goal in delivering PLCS is to improve health outcomes and increase the value of healthcare that pharmacies and pharmacists are able to provide (Moullin, Sabater-Herna, Fernandez-Illimos, & Benrimoj, 2013) .

PLCS is a service provided or supervised by the pharmacist, based on a standardized and structured procedure, to promote optimal health and medicine therapy that is not necessarily medicine/product related (Nutescu & Klotz, 2007).

The scope of practice of community pharmacists in Europe currently includes health promotion, smoking cessation, new medicines service, different types of medication review, among other new and more patient-centred activities. However, there are specific services such as immunization that, although growing, are still scarcely implemented across Europe (Pharmaceutical Group of the European Union, 2017b).

Previous research on the availability of PLCS in Europe includes periodic policy reports issued by the Pharmaceutical Group of the European Union (PGEU), the International Pharmaceutical Federation (FIP) and similar organizations, but also scientific literature. Some countries, such as Portugal stood out as having a wider scope of services available, whilst others were highlighted by having unique services such as pharmacists prescribing in England, Ireland and Northern Ireland (Martins, van Mil, & da Costa, 2015).

The model of practice as well as the implementation of services in primary care varies widely, mainly because of the legal framework and financial incentives for service provision (Martins *et al.*, 2015). Notwithstanding, the international trends suggest a progressive uptake of PLCS in Europe, particularly since 2010, confirming that pharmacists are motivated and capable to acquire and manage new responsibilities in health care systems (Pharmaceutical Group of the European Union, 2010).

Previous research has suggested that the viability of pharmacy services depends heavily on the remuneration models in place. Implementing a new service has associated costs, which include the staff, the training and material resources, to name a few (Latif & Boardman, 2008; Roberts, Benrimoj, Chen, Williams, & Aslani, 2008).

Although there is published literature on the provision of PLCS in Europe, most are not based on a systematic survey with rigid methodology, lack to report the implementation level within the country (or report it in a limited way) and the remuneration models are either absent or superficially described. This study aims to fill in this gap.

1.2 – Aim and objectives

Aim

The aim of this project is to survey the Pharmacist-led Cognitive Services (PLCS) available and performed in primary care across Europe. Additionally, we intended to survey the implementation of PLCS and the associated remuneration models.

Objectives

1. To present the current status of PLCS available in primary care across Europe;
2. To present the implementation level of PLCS available in primary care across Europe;
3. To present the remuneration models of PLCS available in primary care across Europe;
4. To present a detailed description of the PLCS, including the different types of medication review;
5. To analyse the evolution of the availability of PLCS between 2015 and 2017;
6. To analyse the potential relation between the implementation level and the remuneration model of PLCS;
7. To discuss the specific situation in Portugal, the legal framework and the implications of this study findings to the national context;

1.3 – Research question

The research question was deduced from previous research by our group (Martins *et al.*, 2015). An evidence report was composed after a preliminary literature search. Keywords were defined based on the results of this search.

How is the European panorama regarding Pharmacist-led Cognitive Services performed in primary care?

Chapter 2 – Literature Review

2.1 – Community pharmacies in Europe

The role of the pharmacist is established across the world. The pharmacist may practise in various settings and develop a wide range of activities. However, throughout the world the most common practice area is community pharmacy. The community pharmacist performs an essential role in the delivery of better healthcare daily and should be ready to counsel patients' about their health-related problems (World Health Organization, 2011).

According to the FIP, there are 2,824,984 pharmacists that are actively practising. In the EURO region, there are a 8.28 pharmacists' density per 10,000 individuals. In the EURO region 78.5% are working in the field of community pharmacy. The median of pharmacists per community pharmacy in EURO Region is 2.11 with a total number of 1,589,575 pharmacies.

The number of pharmacies per 100,000 inhabitants is not homogenous across Europe. Denmark is the country with least pharmacies per 100,000 inhabitants ($n = 6.55$) contrasting with least pharmacies per 100,000 inhabitants in Greece ($n = 84.06$) (Figure 1).

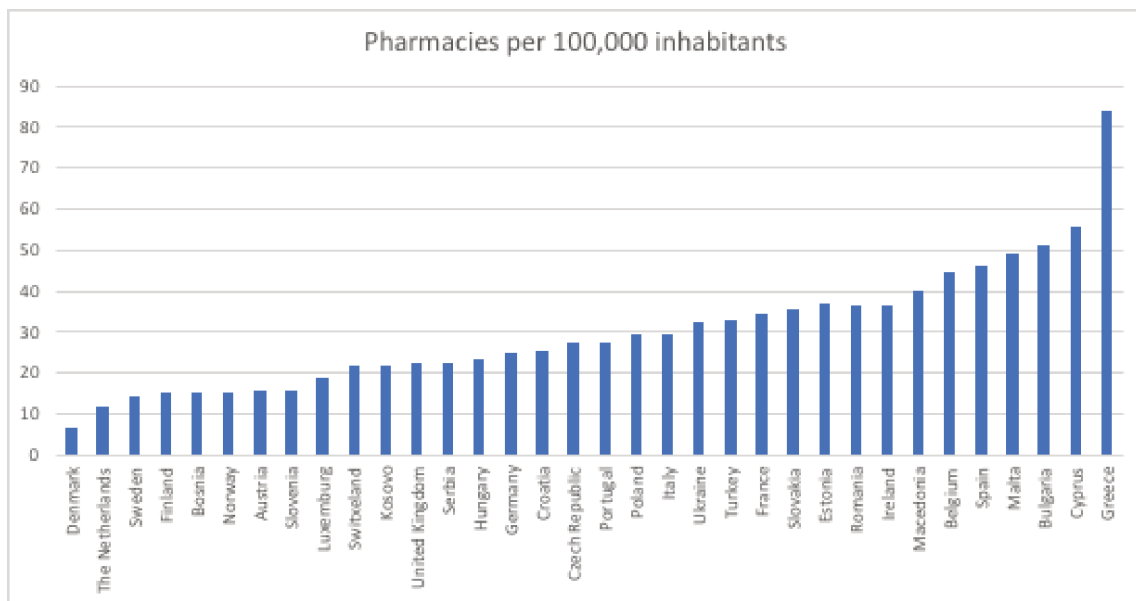


Figure 1 - Pharmacies per 100,000 inhabitants in Europe.

Source: Adapted from (Pharmaceutical Group of the European Union, 2015)

The PGEU released the 2017 annual report, updating some data on this field and describing community pharmacy in 2017. The report showed some positive results regarding the average time for the European Union (EU) citizen to reach the nearest community pharmacy, 58% of the European inhabitants reach the nearest community pharmacy within five minutes and 98% reach within 30 minutes. On average a community pharmacy serves 3,214 citizens and there are 73 pharmacists per 100,000 inhabitants (Pharmaceutical Group of the European Union, 2017b).

In 2013, a study by Martins *et al.*, (2015) aimed to assess the health care and community pharmacy structure in Europe. Results of this study were categorized into sections such healthcare system and community pharmacy. In the community pharmacies the type of products and services is varied across Europe. Besides prescription only medicines and over-the counter-medicines pharmacies can also sell other products such as cosmetics or medical devices.

The regulation of community pharmacies ownership varies across Europe, can either be owned by any individual or entity and there is a possibility to own multiple pharmacies. Within the countries surveyed by Martins *et al.* some criteria were found for establishing new pharmacies. These criteria may be based on distance between pharmacies or number of people served. Most of the pharmacy teams are composed by pharmacists and pharmacy technicians and in some countries can include assistants and nurses. This study discloses major variances between community pharmacy practice in Europe, most of them resulting from the legal framework but also influenced by remuneration issues (Martins *et al.*, 2015).

European Union (EU) pharmacies are evolving towards service provision that aim to go beyond medicines dispensing and result in better health outcomes. Over the last year, some improvements have been registered such as the implementation of specific services. In Norway, there is a new medicine service being piloted, in Portugal a pharmacy-based HIV medicines dispensing is currently being tested where pharmacies dispense antiretroviral therapy (ART) and support people living with HIV (Despacho n.º 199/2016, 2016). In 2018, the Portuguese community pharmacies are allowed to provide point-of-care tests for HCV, HCB and HIV and refer patients to specific units of treatment. These are two examples of new interventions in the community pharmacies

across Europe (Ministério da Saúde, 2018; Pharmaceutical Group of the European Union, 2017b).

Community pharmacists can play an essential role on achieving the ‘triple aim’ which comprises better quality of care, better health outcomes and lower costs (Pharmaceutical Group of the European Union, 2016).

The future embraces a large amount of services offered across European community pharmacies aiming to achieve universal coverage provided by highly qualified and independent healthcare professionals as community pharmacists and medical teams to support the patients, improve public health and the healthcare systems (Pharmaceutical Group of the European Union, 2012).

2.2 – Community pharmacies in primary care

In 1978, primary care was defined by WHO as the “first level of contact for the population with the health care system, bridging health care as close as possible to where people live and work. It should address the main health problems in the community, providing preventive, curative and rehabilitative services” (OECD/European Observatory on Health Systems and Policies, 2016). Primary care assumes there is team work, including the patient at its centre hence there are multiple professionals included in primary care teams. These teams should include multiple HCP such as dentists, dieticians, GP, nurses and pharmacists (European Commission, 2017).

In Europe the number of pharmacies per 100000 habitants and the pharmacists per pharmacist has been increasing, suggesting that primary care is progressively acquiring healthcare professionals (HCPs) that are getting closer to the local communities (Pharmaceutical Group of the European Union, 2010, 2015). Community pharmacies should be recognised, not only for the provision of medicines but also for the provision of pharmaceutical services. It is believed this is the pathway we should take for a better healthcare system (Moullin *et al.*, 2013).

According to the well-known guidance of Good Pharmacy Practice (GPP), pharmacists should be ready to deliver four key services: prepare, store, secure, distribute, administer, dispense and dispose of medical products; deliver effective medication therapy management; develop the professional performance and be contributors to the healthcare effectiveness' improvement and public health. These services can be provided next to the patient in the community by a community pharmacist (World Health Organization, 2011).

In 2016, the FIP presented the “Pharmaceutical Workforce Development Goals”. Goals 7 and 8 refer to professional development, which ensures qualified service provision, adequate workforce training, education and also capable professionals to work in a multi-professional healthcare team. Once these two goals are achieved, countries will be able to deliver patient-centred and integrated health services, whilst also ensuring there are collaborative elements that can be worked through the primary care team (International pharmaceutical Federation - FIP, 2016b).

Worldwide countries started to delivery new care models where the integration of health and social services meets the needs of ageing societies. Non-physician providers, such as pharmacists or nurses, are expanding the roles aiming to maintain access to healthcare and increase the productivity of the health systems. Therefore, the main goal is to improve quality of care for patients (OECD/European Observatory on Health Systems and Policies, 2017).

The World Health Organization (WHO) declare that 70% of all deaths across the globe result from noncommunicable diseases, with 15 million deaths between the ages of 30 and 69 years registered every year. Pharmacists' interventions in the community pharmacy can prevent and promote health to achieve better outcomes in noncommunicable diseases. It is important not only to expand the role of primary care, and fully integrate community pharmacists. This is particularly important for the treatment and prevention of major chronic diseases (World Health Organization, 2013). Looking into the economic figures, deaths from major non-communicable diseases translate into €115 billion in potential economic loss each year. About 1.2 million deaths per year might be avoided with provision of better public health and the development of

policies for disease prevention and health promotion. Similarly, 80% of healthcare costs are allocated to noncommunicable diseases but only 3% of health budgets are spent on prevention. There is a small amount allocated to health promotion and disease prevention (European Commission, 2017; Pharmaceutical Group of the European Union, 2017b).

Some authors recommend that primary care is appropriate for the treatment of ageing patients to preserve the viability of health care. In order to release some work from other HCPs such as physicians and nurses, primary care practices included have a pharmacist to perform and conduct cognitive pharmaceutical services (CPS) that focus on long-term conditions management (Stewart, 2001).

New strategies are appearing, and pharmacists are in the centre of this change. The PGEU, recently released an opinion paper on the Community Pharmacy contribution to Sustainable Health Systems. This paper emphasises the work of the community pharmacist in ensuring access to high quality healthcare, as well as reducing the number of avoidable emergency department visits and hospitalisations. Along with these interventions, the PGEU recommends a series of actions to be prospectively performed and engaged by community pharmacists in order to have a holistic contribution to the healthcare systems. These actions include the expansion of the community pharmacy services as integral part of primary care, better integration of community pharmacists as primary health care services providers, improved access to innovative medicines in the community pharmacies, among others (Pharmaceutical Group of the European Union, 2017a).

Some of the actions proposed involve primary care accessibility to extend to 24 hours a day, 7 days a week and community pharmacies are on the horizon of this strategy, since in most countries access to pharmacy services is available 24/7 through extended opening hours and night services (OECD/European Observatory on Health Systems and Policies, 2016).

There are studies describing the pharmacists' role in primary care and enhancing his contribution to achieve better health outcomes. The social and economic value of the pharmacist integration into primary care teams has been illustrated through multiple studies and systematic reviews (Elliott *et al.*, 2017; Félix *et al.*, 2017; Hazen *et al.*, 2018).

In 2010, a systematic review examined the effect of outpatient pharmacists' non-dispensing roles on patient and health professional outcome such as blood pressure for

the patients and disease control or prevention by the professionals. The professionals can perform a multiply of services and interventions with varied characteristics, such as length of time per intervention and frequency of intervention. For specific diseases interventions, results showed the principal impact in blood pressure control and the smallest in improving COPD or depression outcomes. Authors argue that the smallest effects may be explained by few participants included in such studies, making more difficult to detect the real intervention impact. Generally, pharmacist interventions can lead to improved patient outcomes for multiple disease states, although the results need to be careful interpreted in the absence of statistically significance (Nkansah *et al.*, 2010).

Hazen *et al.*, (2018) performed a systematic review investigating the impact of integrating a non-dispensing pharmacist (NDPs) on medication related health outcome in primary care. The review included 60 comparative studies assessing 89 health outcomes. CPS conducted by NDPs showed a significant positive effect on the assessed health outcomes. In the overall group, the degree of integration of NDPs did not impact health outcomes though the subgroup analysis proposes that integrating a NDP may be relevant for person-centred CPS. Overall, this study suggests that a NDP should be integrated in the care team across the entire patient's pathway, which also includes GPs and nurses. Mention is also made to the importance of including follow-up reviews and to improve the communication with the patient's GP to achieve fully integrated care and consequently better outcomes (Hazen *et al.*, 2018).

A 6-month study conducted in community pharmacies in Belgium assessed pharmacists' provision of inhalation technique in asthma, considering adult asthma control as the outcome of interest. Patients with uncontrolled asthma showed improvements at the end of the study. Both inhalation technique and adherence to controller medication were significantly better. The results of this study demonstrate that community pharmacists can complement asthma education and can provide patient-focused care on correct use of medicines for asthma, which will lead to improved overall outcomes on asthma treatment in primary care (Mehuys *et al.*, 2008).

A systematic review aimed to synthesize cost-effectiveness analyses on services performed in Europe. Twenty-one studies were identified in different European countries,

including the United-Kingdom, the Netherlands, Spain, Belgium, France and Denmark. National strategies were developed in these countries to integrate pharmacists in primary care and also to remunerate them for the provision of services. These cost-effectiveness studies can facilitate the implementation and expansion of services in the European setting, as well as lead to the development of remuneration strategies' by facilitating stakeholders' decisions. Furthermore, some of these services have demonstrated to contribute to the improvement of public health, notably those of screening or smoking cessation (Perraudin, Bugnon, & Pelletier-fleury, 2016).

More recently, an Italian study evaluated the effectiveness and cost-effectiveness of Medicines Use Reviews (I-MUR) provided by community pharmacists in asthma patients. The authors reported evidence of superiority for this service compared with standard care. After the intervention the number of medicines used was decreased and medication adherence improved, in 35.4% at 3 months and by 40.0% at 6 months. The probability of the service being cost-effective went from 51.5% at 3 months to 100% at 9 months. Adherence proved to be a key factor to asthma control, and a factor where pharmacists can be major influencers in primary care (Manfrin, Tinelli, Thomas, & Krska, 2017).

In 2002, a program evaluated the effectiveness of a pharmacist-led smoking-cessation plan using quality of life as the primary outcome. Results suggest that weekly sessions between pharmacist and smoker over 12 weeks can increase quality of life in the first few months of treatment, and 3 months after total cessation. The authors conclude that pharmacists can effectively lead the patient to smoking-cessation habits through behaviour interventions and counselling (Zillich, Ryan, Adams, Yeager, & Farris, 2002).

A Portuguese study intended to estimate the social and economic benefits of current and potential future CPS in Portuguese community pharmacies. From the social perspective, there was an estimated 8.3% annual increase in Quality of Life (QoL) from CPS provided in the pharmacy. When considering potential future services, the authors claim these could be responsible for an additional increase of 6.9% in QoL. The economic value of CPS was estimated to be equivalent to 879.6 M€, attributable mostly to the avoided health supply consumption. The generated savings represented 0.5% of the GDP, in 2014. The studies considered for the estimates reported improved outcomes in various areas, including diabetes, hypertension, asthma or dyslipidaemia (Félix *et al.*, 2017).

Even though there is real-world evidence that supports the presence of a pharmacist in primary care, there are barriers and facilitators experienced by pharmacists who are recently integrating a primary care team. A study led by Canadian pharmacists revealed seven key themes describing barriers and facilitators experienced during the pharmacist integration in these teams, such as relationships; pharmacist role definition; orientation and support; professional experience; pharmacist presence; resources and funding and value of the pharmacist role. These studies can be seen as foundation work to find the useful role of the pharmacist into the full integration of the pharmacist in primary care teams. Additionally, this evidence may also be helpful for policymakers and researchers to develop practice guidelines to facilitate the integration process across an entire country.

The ultimate goal is to keep the volume of integrated care initiatives that are already under development and implemented (Figure 2), but also to produce better policies, including considering all health care professionals as integral to primary care teams.

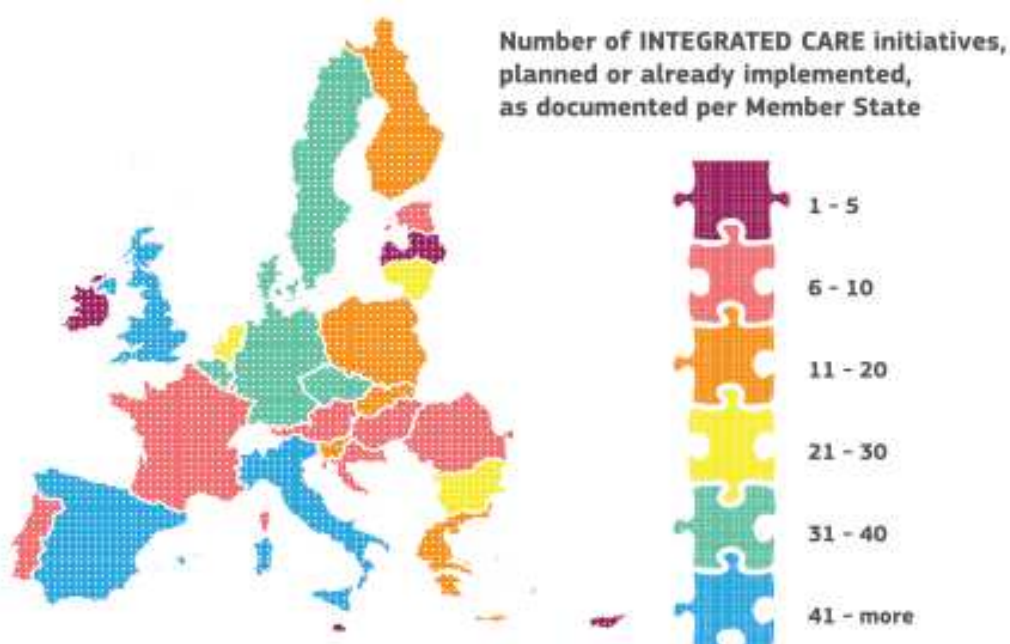


Figure 2 - Integrated care initiatives implemented in Europe.

Source: (European Commission, 2017)

2.3 - Pharmacist's Role in Person-centred care

Person-centred care, more commonly referred as patient-centred care in the medical literature, has several definitions, but they all focus on incorporating important components across the patient pathway. Patient-centred care can be defined as: “the care that incorporates use of clinician skills, evidence-based knowledge and patient perspective to provide personalized, co-ordinated care which enables people to make the most of their lives” or “care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensures that patient values guide all clinical decisions” (The health foundation, 2014).

Therefore, a quality patient experience can be enhanced with some components along the patient pathway. Researchers have developed work in this area and after conducting interviews and experiences between caregivers and patients reached a consensus which results in the eight dimensions of patient-centred care (Figure 3).

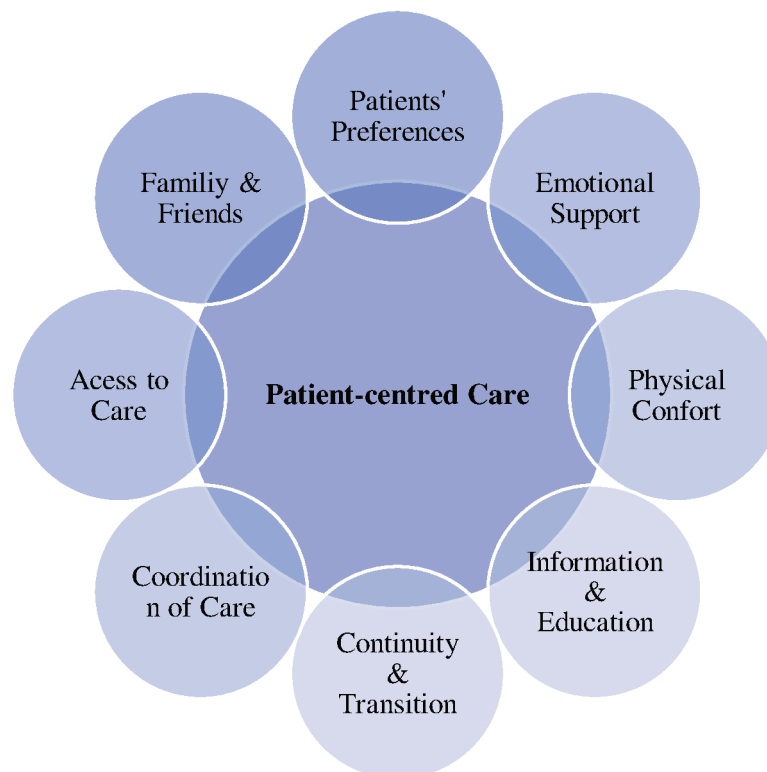


Figure 3 - Picker's Eight Dimensions of Patient-Centred Care.

Source: Picker Institute's, 1987

The role of the pharmacist has been changing and diversifying from a product to a patient-centred view. Along the 21st century the pharmacist follows this process and continues to move towards patient-centred practice (Cipolle, Strand, & C. Morley, 2012).

The FIP/WHO, (2006) define a pharmacist as a “person professionally qualified in pharmacy, the branch of health sciences dealing with the preparation, dispensing and use of medicines. The role of the pharmacist has evolved from that of a provider of medicines to that of a provider of patient-centred pharmaceutical care”. This definition encourages the pharmacist to make a patient-centred approach in every intervention.

The pharmacist’s focus is not only on the medications but should embrace the patients, his condition and his medication management. This description can have multiple terms such as: medication therapy management, pharmaceutical care or cognitive services. Pharmacists develop their functions in pharmacy practice and have increased responsibility and liability towards the patient. (Sleath, Rubin, Campbell, Gwyther, & Clark, 2001).

Aside with this modification, pharmacists’ competences and professional development also evolve. Professionals are engaging in new areas of knowledge and research to ensure quality by delivering new services (FIP Pharmacy Education Taskforce, 2010).

Along with this strategy, the FIP makes a recommendation lined up with this view. It suggests that the countries should follow a strategy wherein a patient-centred and integrated health services basis is relevant to social determinants of health and needs-based approaches to pharmacists’ development (International pharmaceutical Federation - FIP, 2016b).

During this patient’ care process, the pharmacist must learn with the patient, his attitudes and beliefs, attitudes, behaviours toward health, disease and medications; it is necessary to understand that different individuals have unique experiences. This pharmacist and patients’ openness offers as a way of “balancing the equation” for the

pharmacist in the 21st century (Crespo-Gonzalez, Garcia-Cardenas, & Benrimoj, 2017; De Oliveira & Shoemaker, 2006).

In 2014, the Joint Commission of Pharmacy Practitioners produced a patient-centred care process that comprises five principles: collect, assess, plan, implement and follow-up (Figure 4). This strategy should be ensured in collaboration with other HCP in the healthcare team to optimize patient health and medication outcomes. The first stage is to promote a relationship between the pharmacist and the patient that lasts and produces effective communication throughout the process.



Figure 4 - Pharmacists' Patient care process.

Source: Joint Commission of Pharmacy Practitioners, 2014

This process shows that pharmacists can have an essential role on this patient-centred approach and can work in direct collaboration with other HCPs in order to deliver high quality, cost-effective and accessible health care for patients (Joint Commission of Pharmacy Practitioners, 2014).

The Royal Pharmaceutical Society, (2013) issued a detailed approach to medicines optimisation (Figure 5). These principles are based on a patient-centred approach and in which the patient and the pharmacist are engaged to each other keeping in mind that the ultimate goal is to improve patient outcomes.

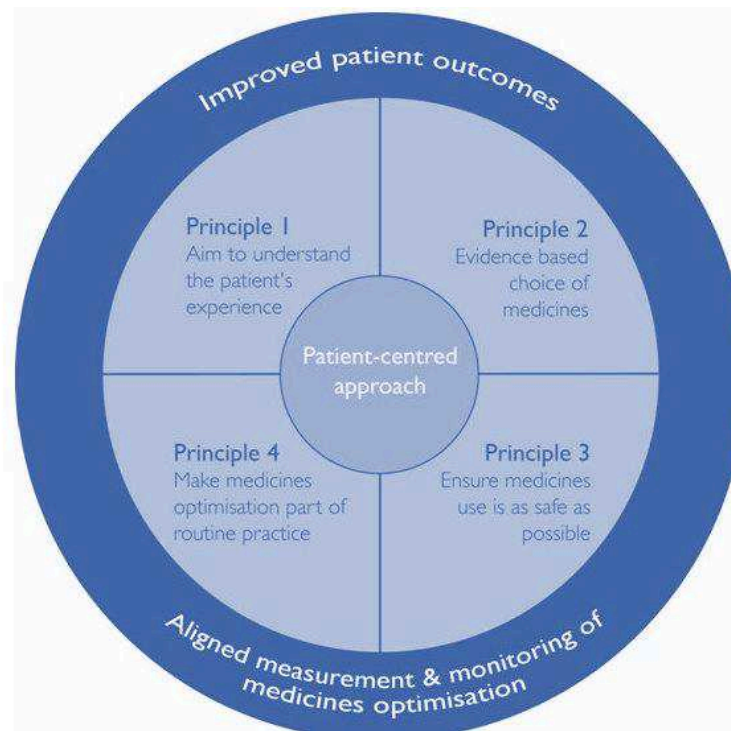


Figure 5 - The four guiding principles of medicines optimisation.

Source: Royal Pharmaceutical Society, 2013

Medicines optimization is part of pharmaceutical care that every pharmacist should deliver, which should also be patient-centred practice focusing on detecting, solving and avoiding medicines' therapy problems (FIP/WHO, 2006).

During the process of medication review it is important that the patient is present and participates actively with the pharmacist in the dialogue. When this service is provided only with limited information about the patient, there are gaps that cannot be filled (McKain & O'Neil, 2015).

Overall, patient-centred care should be recognized as a global strategy and as a priority approach for pharmacy practice. This approach is particularly important in patients that have multiple conditions. It is also important to acknowledge that an optimal evidence-based practice requires pharmacist's knowledge and recognition of the patients' values and preferences (Barnett, Oboh, & Smith, 2016).

2.4 – Pharmacist-led Cognitive Services

2.4.1 – Pharmaceutical Care

Since 1975, when the term pharmaceutical care was first defined by Mikeal as “the care from anyone for their patient in order to assure safe and rational drug usage”, the concept of pharmaceutical care has evolved (L Mikeal, R Brown, L Lazarus, & C Vinson, 1975).

Some authors defend that the definition by Hepler and Strand in 1990 is the first official definition, stating that “Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life” (Hepler & Strand, 1990).

However, there is a lack of patient-centred approaches and new definitions start to appear. In 2013, the Pharmaceutical Care Network Europe (PCNE) issued a position paper stating that “Pharmaceutical care is the pharmacist’s contribution to the care of individuals in order to optimize medicines use and improve health outcomes.” (Allemann *et al.*, 2014)

It seems clear that European countries are making an effort to embrace pharmaceutical care into their daily practice. Nevertheless, the lack of harmonization in primary healthcare and in the healthcare systems, transforms this process into a demanding task. Therefore, the definition of pharmaceutical care is still under continuous discussion (Melton & Lai, 2017).

Even though the term ‘pharmaceutical care’ is well-known as a philosophy of practice it is important to keep in mind that it assembles several services in different countries across Europe. It is expected that the delivery of this service is improved when other services are provided, such as medication review or medication adherence enhancing programs (F. A. Costa *et al.*, 2017; Roughead, Semple, & Vitry, 2005).

Accordingly, pharmaceutical care cannot be provided independently from other health care services and it requires a full collaboration with the healthcare team (F. van Mil & Schulz, 2006).

Several countries are providing pharmaceutical care related services. Most of these are disease-oriented pharmaceutical care. In Portugal there are programs for diabetes; asthma and COPD; and hypertension and hyperlipidaemia. In the UK, there are programs designated to prevent medication errors during and after the dispensing process.

The implementation and practice model of pharmaceutical care is varied between countries that are influenced by the different perspectives of pharmaceutical care and pharmacy practice (European Directorate for the Quality of Medicines & HealthCare - EDQM, 2012; Farris, Fernandez-Llimos, & Benrimoj, 2006)

In 1994, the PCNE was created under the coordination of Prof. Hanne Herborg in Hillerød (Denmark). It is an official association since 2004. This network had three main goals: to generate projects, to raise funds among the summons of European projects and to assist those countries whose professionals are still reluctant to embrace pharmaceutical care. Nowadays, the aim of this organization is helping its members to develop pharmacy along the lines of pharmaceutical care. This work is based on the development of pharmacy by encouraging pharmaceutical care in Europe and also by motivating research in this area (Pharmaceutical Care Network Europe, 2010).

Under these circumstances, two studies aimed to assess the implementation level of pharmaceutical care using a standardised scale aimed for pharmacists' self-report based on the last individuals served at the pharmacy.

The first study in 2006 concluded that the provision of pharmaceutical care was still limited in Europe and there was still major room for improvement. The community pharmacists were performing general activities such as patient record screening but were less involved in patient centred activities such as the implementation of specific pharmacotherapy management programs. It also concluded that pharmacist who had the support of other pharmacists had more time to perform services where the provision of pharmaceutical care was intended. These studies yielded unexpected results with Ireland appearing as the highest scoring and Denmark as the lowest scoring country (Hughes *et al.*, 2010).

In the previous year of this study, Cabrera, Núñez, Baena, Fajardo, & Fernando (2005) identified that the three main barriers for the provision of pharmaceutical care were: lack of time, lack of training and education in pharmacotherapy management and unfamiliarity regarding drug-related problems (Cabrera *et al.*, 2005).

Ten years later the study was replicated and found particularly improvements in Denmark and Switzerland, aside with a wider country application of pharmaceutical care.

Although this study suggested a slight improvement in the availability of pharmaceutical care in European countries, there were still some barriers acknowledged that needed to be overcome such as, lack of time and resources in the pharmacies. This recent study also indicates that there is a lack of consistency in the provision of pharmaceutical care. It is also acknowledged that the delivery of pharmaceutical care, along with other patient-centred services, is hard to implement perhaps because in most countries there are still no motivators. (F. A. Costa *et al.*, 2017).

It has been identified that several interventions under the term pharmaceutical care such as medication reviews, can improve medicines management in older people; hypertension management in Portugal; asthma-related quality of life in Denmark and Malta; and also, various European studies that express general improvements in quality of life, aside with positive opinions of pharmacists and GPs (Meid, Lampert, Burnett, Seidling, & Haefeli, 2015; Posey, 2003; Roughead *et al.*, 2005).

2.4.2 – Pharmaceutical Services

Definitions

In the field of pharmacy practice and service provision, as in others in constant evolution, it is important to find common terms and definitions, especially for the purpose of worldwide comparison. The perception of definitions is different across countries and languages. It is necessary to ensure that terminology is defined and used consistently (J. W. F. van Mil & Henman, 2016).

The concept of pharmaceutical services includes the services summarised by pharmacists and pharmacy staff to support the delivery of pharmaceutical care. Under this reason there are a number of tasks that pharmacists must enclose in their daily practice in order to provide the best care to the patients (FIP/WHO, 2006).

The concept of pharmacy service has diverted through the years since pharmacists have started to make a complete patient's approach, not only based on drug therapy but also aiming for improved patient's outcomes. There is not an universal definition stated in the literature that includes all the services and programs provided in the pharmacy (Moullin *et al.*, 2013). As such, the term cognitive pharmaceutical services (CPS) was adopted to ensure that important aspects in the pharmacist role were being incorporated.

CPS can be seen as a range of healthcare-related activities (some of them including pharmaceutical care) to enhance public health and the quality of drug therapy, promoted by the pharmacy staff (Hopp, Sørensen, Herborg, & Roberts, 2005).

Professional pharmacy services are integrated in the complete service offered by the community pharmacy (Figure 6). Community pharmacies can provide professional services and non-professional services. Professional services encompass a specific health knowledge while the non-professional concern non-technical tasks, like human resources, that are not directly related with improving patient's health. Most of pharmacy research has focused on the pharmacist-led services, however the other HCP are also providing some professional services. Pharmaceutical services may include various services that ultimately effort to integrate the concept of pharmaceutical care into practice. Pharmaceutical Services are related to medicines' management including pharmaceutical care services and cognitive pharmaceutical services. Other services can be included in this concept such as health promotion integrated in primary care. The ultimate goal is to improve the value of healthcare (Moullin *et al.*, 2013).



Figure 6 - Pharmacies Services Model

Source: Moullin *et al.*, (2013)

Roberts *et al.*, (2005) defined CPS as: “the use of specialized knowledge by pharmacists for the patient or health care professionals for the purpose of promoting effective and safe drug therapy”.

According to Nutescu & Klotz (2007), Pharmacist-led cognitive service (PLCS) is a service provided or supervised by the pharmacist, based on a standardized and structured procedure, to promote optimal health and medicine therapy that is not necessarily medicine/product related (adapted). This definition integrates all the components for the pharmacist to provide a service to the patient.

Through the years, the community pharmacy is facing a change from the concept of pharmaceutical care to the concept of cognitive pharmaceutical services that ultimately requires for the pharmacist to arrange some strategies to better sustain his healthcare provision but also the community pharmacy business.

CPS can be hierarchized into levels of differentiation (Figure 7) (Benrimoj, Feletto, Gastelurrutia, Martinez Martinez, & Faus, 2010).

Levels	
1	•Medicines Information
2	•Compliance, Adherence and/or Concordance
3	•Disease Screening
4	•Disease Prevention
5	•Clinical Intervention or Drug Related Problems
6	•Medication Use Review
7	•Medication Therapy Management
8	•Disease Management for Chronic Conditions
9	•Participation in Medical Decisions
10	•Prescribing

Figure 7 - Hierarchical Model of CPS

Source: Benrimoj *et al.*, 2013

Correr, Rotta, Salgado, & Fernandez-Llimos, (2013), performed a study that aimed to describe pharmacist services assessed by systematic reviews and to qualitatively identify the main categories of the pharmacist intervention. The group identified eight categories of services, which were divided into the main goals: patient counselling, risk factors prevention and control, adherence/compliance, medication review, pharmacotherapy follow-up, medication reconciliation, elaboration of protocols with other HCPs in the team (Table 1; Correr *et al.*, 2013).

Table 1 - Description of categories for cognitive pharmaceutical services

Source: Adapted from Correr *et al.*, (2013)

Categories	Description
Patient Counselling	<p><u>Aim:</u> Medicines optimization</p> <ul style="list-style-type: none"> • Patient Counselling on medicines and diseases (integrated or separated from medicines dispensing).
Risk factors prevention and control	<p><u>Aim:</u> Risk factors prevention</p> <ul style="list-style-type: none"> • Promotion of health screening programs, smoking cessation counselling, point-of-care tests.
Adherence/compliance support and monitoring	<p><u>Aim:</u> Patient adherence and compliance</p> <ul style="list-style-type: none"> • Adherence support and monitoring to the patient. This may be achieved using different methods (<i>e.g.</i> questionnaires, prescription refill pill count, etc).
Medication review and pharmacotherapy follow-up	<p><u>Aim:</u> Identify and support the medicines uptake by the patient</p> <ul style="list-style-type: none"> • Evaluation of a patient's medicines with the aim of optimising medicines use and improving health outcomes.
Elaboration of protocols with other HCP	<p><u>Aim:</u> Elaboration of protocols with other HCP in multidisciplinary teams</p> <ul style="list-style-type: none"> • Pharmacist become a prescriber integrated in a multidisciplinary team.

The expansion and differentiation of community pharmacy practices and the expansion of the pharmacists' role showed to be professionally advantageous (Farris *et al.*, 2006).

2.4.3 – Implementation and sustainability of PLCS

Curran *et al.* (2012) defined implementation as “an effort specifically designed to get best practice findings and related products into routine and sustained use through appropriate change/uptake/adoption interventions”. This definition is adaptable to services definition, so it is necessary to take into consideration the implementation but also the sustainability of the service (Curran, Bauer, Mittman, Pyne, & Stetler, (2012).

Through the years, the number of CPS provided across the world is increasing, albeit there is some discussion around the implementation of these services. Studies suggest that a number of services are not being sustained or are not being delivered as they were intended for.

The core concepts of implementation are: the process of implementation, the innovation (professional pharmacy service), the contextual domains effected by factors, strategies and evaluations (Moullin, Sabater-Hernandez, Fernandez-Llimos, & Benrimoj, 2015).

Moullin, Sabater-Hernández, & Benrimoj, (2016) applied the concept of the generic implementation framework to the context of services in the community pharmacy which resulted into the Framework for the Implementation of Services in Pharmacy (FISpH) (Figure 8).

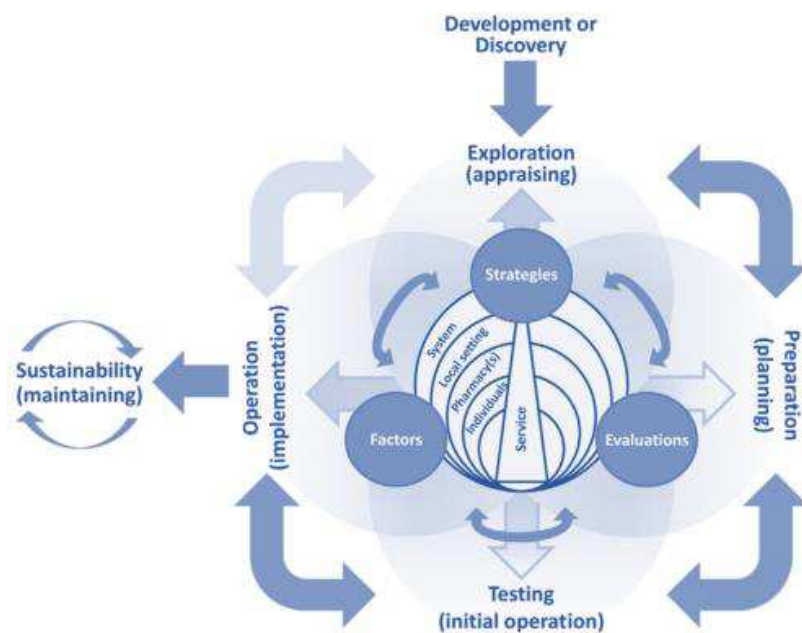


Figure 8 - Framework for the Implementation of Services in Pharmacy (FISpH)

Source: Moullin, Sabater-Hernández, & Benrimoj, (2016)

In order to implement a successful service in a community pharmacy, Moullin *et al.* recommend a series of steps and stages should be followed (Figure 9).

These steps include the discovery, the exploration, to assess the value or the characteristics of the service; preparation, to organise supporting conditions or to provide some additional training; testing, for example the patient demand; operation, set the goals, modification of plans and procedures and last, sustainability in the pharmacy. This process can be adapted either to the implementation of new services or to ensure the sustainability of existing services in these pharmacies (Moullin, Sabater-Hernández, & Benrimoj, 2016b).

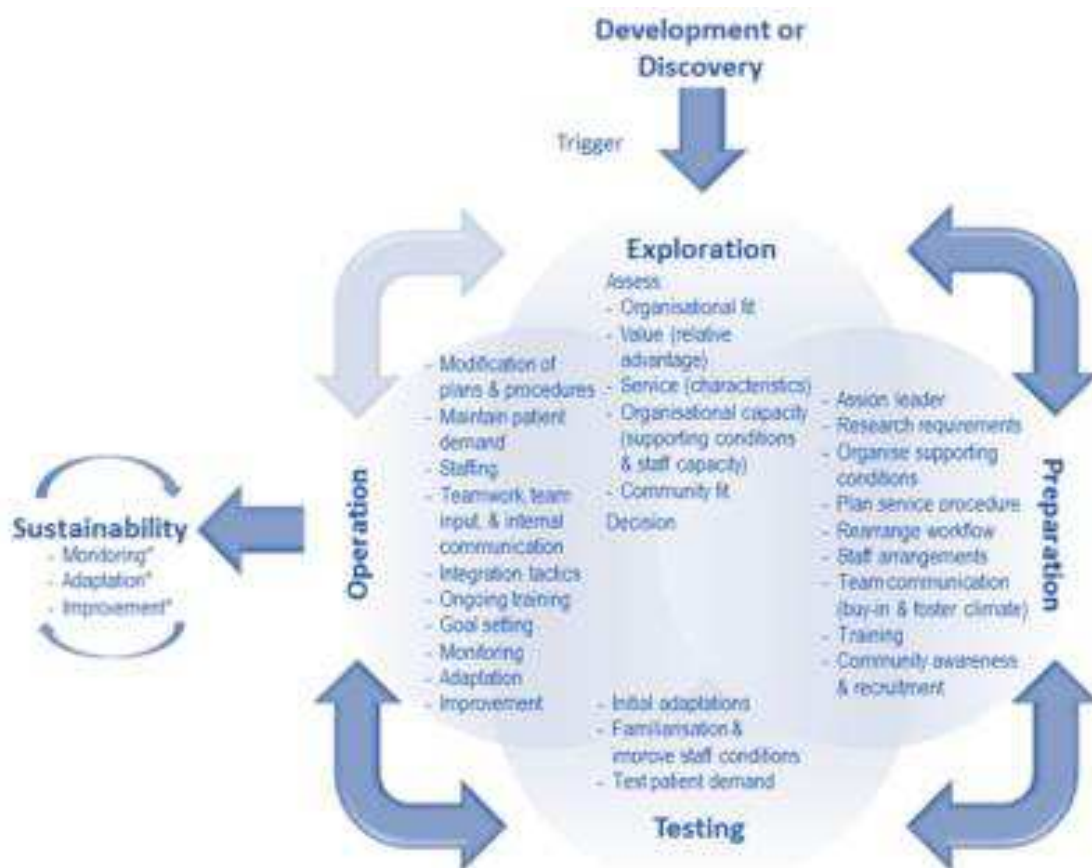


Figure 9 - Process of implementation in community pharmacy

Source: Moullin, Sabater-Hernández, & Benrimoj, (2016b)

To keep a sustained implemented service is important to plan and implement monitoring systems, to have financial resources to support the services with trained and motivated staff. The community pharmacy is a small business with a limited financial

capacity to develop innovation, so it is important to evaluate first and after that, make a successful implementation.

The community pharmacies are evolving towards a model that can implement these services daily. Changes are incorporating dedicated areas for service provision or change the design to identify the pharmacy as a service provider.

In order to build capacity to implement and sustain services, the Framework for the Implementation of Services in Pharmacy (FISpH) showed useful results, in a way that the service is in the centre of action where all service resources are available together.

The capacity to incorporate new services in the daily practice over the time that will eventually sustain the community pharmacies (Feletto *et al.*, 2010; Garcia-Cardenas, Perez-Escamilla, Fernandez-Llimos, & Benrimoj, 2017).

After conducting the implementation process is essential to find a model that can evaluate the impact of such implementation (Figure 10).

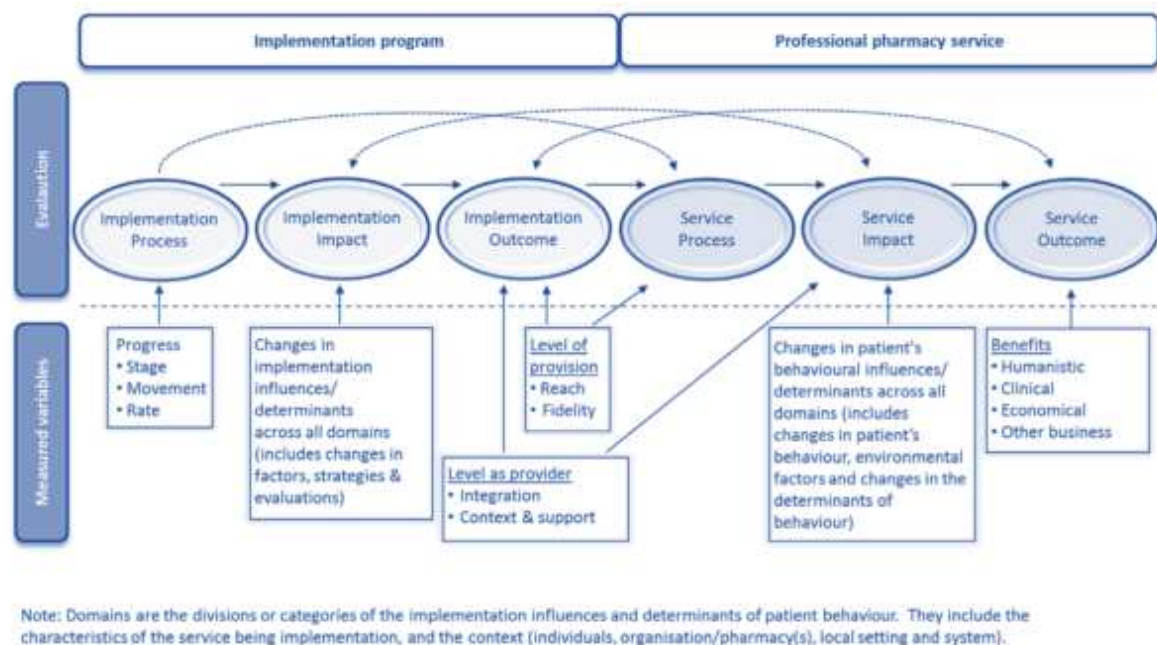


Figure 10 - Model for the evaluation of implementation of CPS

Source: (Moullin, Sabater-Hernández, & Benrimoj, 2016a)

The proposed evaluation model includes indicators for implementation and service. These indicators are subdivided into process, impact, and outcome. Within each

stage of the model, a number of variables is measured according to each service being provided (Moullin, Sabater-Hernández, & Benrimoj, 2016a).

After the process of implementation and the evaluation, the service should be sustainable. Sustainability can be measured according to three main ideas: routinization, which means the establishment of the service into daily routine; institutionalization to find the conditions to support the service and the preservation of benefits. More than looking for the level of provision, community pharmacies should be aware of the context they are enclosed. These models for evaluation should be adapted to the necessities of the pharmacy to help understand and predict implementation outcomes (Feletto *et al.*, 2010; Moullin, Sabater-Hernández, & Benrimoj, 2016a).

An holistic approach to PLCS implementation is described in a model proposed by Benrimoj *et al.*, (2010). Figure 11 describes the holistic approach to service implementation based on an analysis of historical developments, practice experience and evidence-based research.

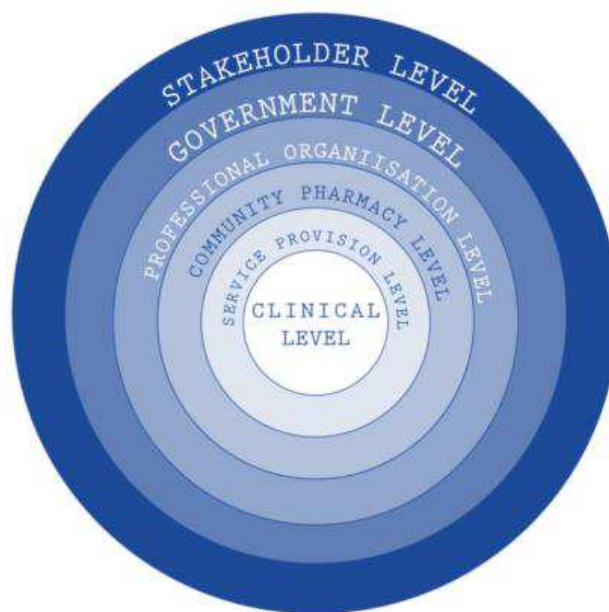


Figure 11 - Holistic approach to service implementation

Source: Benrimoj *et al.*, (2010)

An example of the holistic approach applied in practice is the conSIGUE study. This study emerged in January 2008 from a group of Spanish leading politicians, professional pharmacy associations who gathered to plan the changing role of pharmacy.

The aim was to find consensus for the provision of three key CPS through community pharmacies.

Seguimiento Farmacoterapéutico (SFT) is a medication management service studied. Because it was considered a National strategy (top-down approach), a specific and holistic program was designed aiming for support from stakeholders, professional organizations to set up the service effectively in the pharmacies. Research has suggested that pharmacist training needs to be supported by individualized assistance over time to encourage CPS implementation and sustainability (bottom-up approach).

It is important for the pharmacist to engage with all the professionals and the issues integrated in the holistic approach to contribute into successful patients' outcomes.

The second phase of this project consisted in evaluating the conSIGUE implementation and the implementation effectiveness. The health outcomes were evaluated under routinization using the effectiveness—implementation design. Data suggested SFT is a highly effective service and that the future implementation in pharmacies may be essential to sustain the health system (Benrimoj *et al.*, 2010; Fernández-Rodríguez *et al.*, 2016).

The use of these models and frameworks to simplify the implementation of health innovations has been widely recognized and can shorten the breach between evidence and practice (Garcia-Cardenas, Benrimoj, *et al.*, 2017).

Sustainability is a crucial it is necessary to maintain the provision of the service. Crespo-Gonzalez *et al.*, (2017) defined sustainability as “a phase in the process of a professional pharmacy service, in which the service previously integrated into practice during the implementation phase is routinized and institutionalized over time to achieve and sustain the expected service outcomes”. Two key concepts are identified: routinization and institutionalization.

The future role of the pharmacists encompasses predominantly the provision of services, so the definition of these terms is important and can work as a basis for future research into implementation and sustainability of pharmacy services.

2.4.4 – Availability across Europe

The international trends suggest a progressive uptake of PLCS in Europe, particularly since 2010, confirming that pharmacists are motivated and capable to acquire and manage new responsibilities in health care systems (Pharmaceutical Group of the European Union, 2010).

The scope of practice of community pharmacists in Europe currently includes health promotion, smoking cessation, new medicines service, different types of medication review, among other new and more patient-centred activities. However, there are specific services such as immunization that, although growing, are still scarcely implemented across Europe (Pharmaceutical Group of the European Union, 2017b).

The PGEU is an organization that represents the community pharmacy perspective across Europe. This group sustains a relation to legislative and policy initiatives at the EU level that are directly linked to our profession and/or public health.

According to the Pharmaceutical Group of the European Union, (2010) pharmacy services can be clustered into three categories according to their complexity and demands. The categories include core services, basic services and advanced services. This classification assumed there are (Figure 12):

- **Core Services:** essential services provided by all licensed pharmacies during core pharmacy opening hours.
- **Basic Services:** may require separate consultation facilities and special training of pharmacy staff; may need to be available outside core pharmacy opening hours (*e.g.* during the night)
- **Advanced Services:** require separate consultation facilities in the pharmacy and accredited pharmacists to provide it.

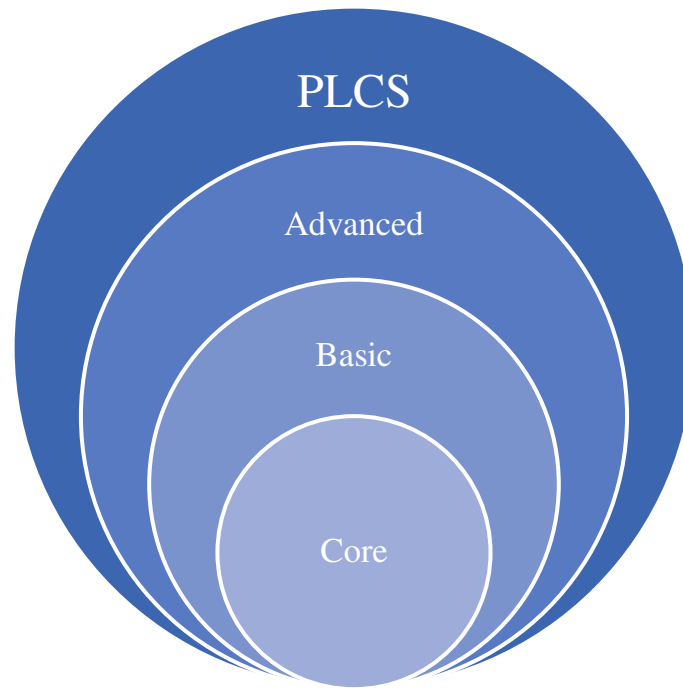


Figure 12 - Graphic representation of services classification

Source: Pharmaceutical Group of the European Union, (2010)

These services are designed intended to promote health in specific programs, to provide specific advices to promote health and prevent illness or to help those who wish to quit smoking or that need help with their medication.

Since 2010, the PGEU issues an annual report where it states the number of pharmacy services provided in community pharmacy, either by a pharmacist or by another HCP.

Across the years there is a tendency for the number of services to grow and for emerging new services such as new medicines service and needle and syringe exchange.

Figure 13 provides an overview on the evolution of the number of European countries providing PLCS. In general, the provision of services is increasing across Europe. There are some services that stand out for the strong growth such as medicines use review, vaccination and the services that can be aggregated into one service like point-of-care testing (blood pressure measurement, weight measurement, glucose measurement, cholesterol measurement).

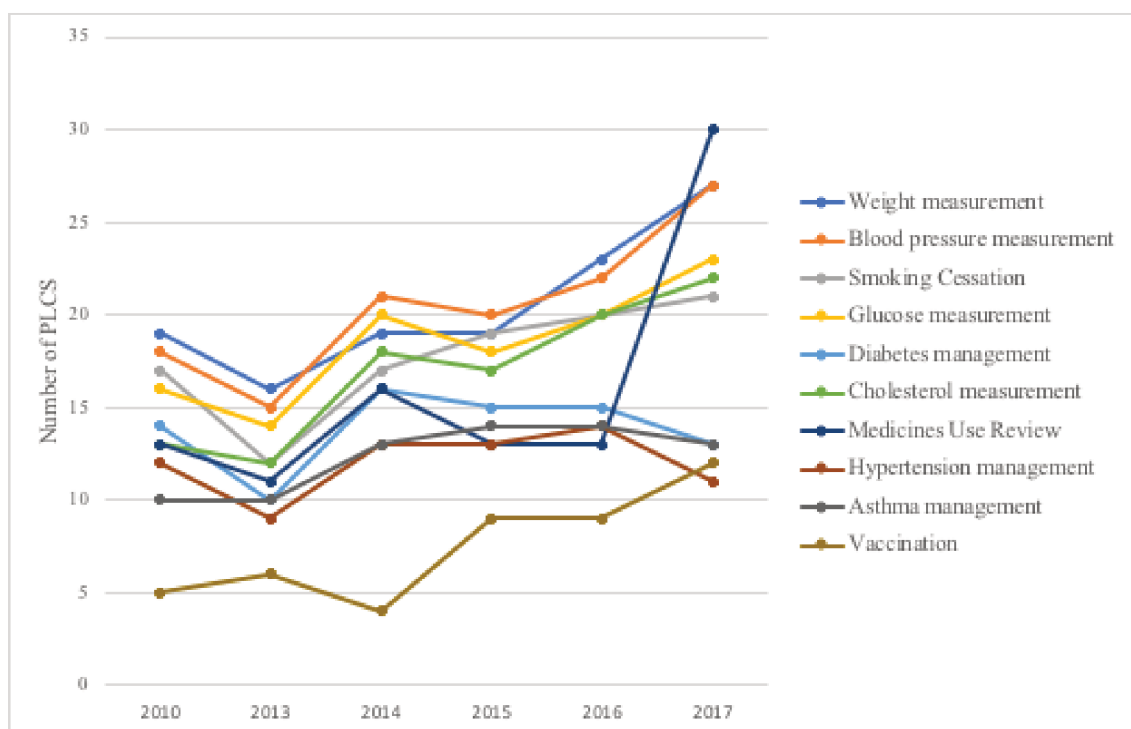


Figure 13 - Evolution of the number of European countries providing person-centred services

Source: PGEU Annual Reports 2010-2017

An overview of the available services in community pharmacy reported by Martins et al., 2015 is presented in Table 2. Comparing this source with the PGEU Annual Report from 2013, we can see the number of countries providing vaccination ($n=6$), and medicines use review ($n = 11$) was equal in both sources. Additionally, there are similar results for homecare services and biological parameters. The services more widely provided in European pharmacies are smoking cessation programmes, drug waste management programmes and pharmaceutical care programmes. Drug administration and prescription services ($n = 5$) were the least reported available services. The results of this study were similar to the results of Kanavos *et al.*, (2011) also reporting the wide dissemination of smoking cessation and drug waste management. These findings can indicate that pharmacists are covering the public health sector and patients' demands to improve their quality of life (Kanavos *et al.*, 2011).

Table 2 - PLCS available in Europe in 2015

Country	Home care support	Administration of injectable medicines	Administration of vaccines	Medical appointments (e.g. nutrition consultations)	Measurement of biological and biochemical parameters	Pharmaceutical care programs	Smoking cessation programme	Needle exchange programme	Medication review	Drug waste management programme	Prescribing	Provision of written standardized information
Belgium	Yes ¹	No	No	No	No	Yes ¹	Yes ¹	Yes ^{1,2}	No	Yes ^{1,2}	No	Yes ^{1,2}
Bulgaria	No	No	No	Yes ¹	Yes ¹	Yes ¹	Yes ¹	×	Yes ¹	×	No	Yes ^{1,2}
Croatia	No	No	No	Yes ¹	×	No	Yes ¹	×	No	Yes ¹	No	No
Denmark	Yes ¹	No	No	No	Yes ²	Yes ^{1,2}	Yes ^{1,2}	No	Yes ¹	Yes ^{1,2}	No	No
Spain	No	No	No	Yes ²	Yes	Yes ¹	Yes ¹	Yes	Yes ¹	Yes ¹	No	Yes ¹
Netherlands	Yes ¹	No	No	Yes ¹	Yes	Yes ¹	Yes ¹	Yes	Yes ¹	Yes	No	Yes
Hungary	No	No	No	Yes ¹	Yes	Yes ¹	Yes ¹	No	Yes ¹	Yes ^{1,2}	No	No
England	Yes ¹	Yes ¹	Yes ¹	Yes ¹	Yes	Yes ¹	Yes ¹	Yes	×	Yes	Yes	Yes
Ireland	No	×	Yes ¹	×	Yes ^{1,2}	No	×	Yes	No	Yes	Yes	No
N. Ireland	No	No	Yes ¹	No	No	Yes ¹	Yes ¹	Yes	Yes ¹	Yes ¹	Yes ¹	No
Iceland	No	No	Yes ²	Yes	Yes	No	Yes	No	No	Yes	No	No
Italy	Yes ¹	No	Yes ¹	Yes ¹	Yes	Yes ¹	Yes ¹	Yes	Yes ¹	Yes ¹	No	Yes ¹
Macedonia	No	Yes ^{1,2}	No	No	Yes ²	No	No	No	No	No	No	No
Malta	No	No	No	Yes	Yes ¹	No	No	Yes	No	No	No	No
Norway	No	No	No	Yes ¹	No	Yes ¹	Yes ¹	Yes	Yes ¹	Yes	No	Yes
Portugal	Yes ¹	Yes ¹	Yes ^{1,2}	Yes ²	Yes ¹	Yes ¹	Yes ¹	Yes	Yes ¹	Yes ^{1,2}	No	Yes ^{1,2}
Serbia	No	No	No	No	No	Yes ¹	No	No	Yes ¹	No	No	Yes
Sweden	Yes ^{1,2}	No	No	No	No	Yes ^{1,2}	Yes ^{1,2}	No	Yes ^{1,2}	Yes ^{1,2}	No	Yes ^{1,2}
Switzerland	Yes ²	Yes ¹	No	Yes ²	Yes ¹	Yes ¹	Yes	Yes	No	Yes ²	No	Yes ²

Source: Adapted from (Martins *et al.*, 2015)¹ Performed by pharmacists² Performed by other HCP

The FIP is a global non-governmental organisation that represents four million pharmacy and pharmaceutical sciences all over the world through 140 national organizations that can be academic institutional or individual members. Its main goal is support the development of the pharmacy profession, enhancing practice and scientific innovations based on world's health care needs and expectations (FIP - International Pharmaceutical Federation, 2018).

In 2017, the FIP issued a report providing an overview on the pharmacy profession between 2015 and 2017. Sixty-nine countries responded to the community pharmacy part of the survey. One of the surveyed areas was the pharmacists' activities in the pharmacy including the services available and the associated costs of the services (Figure 14).

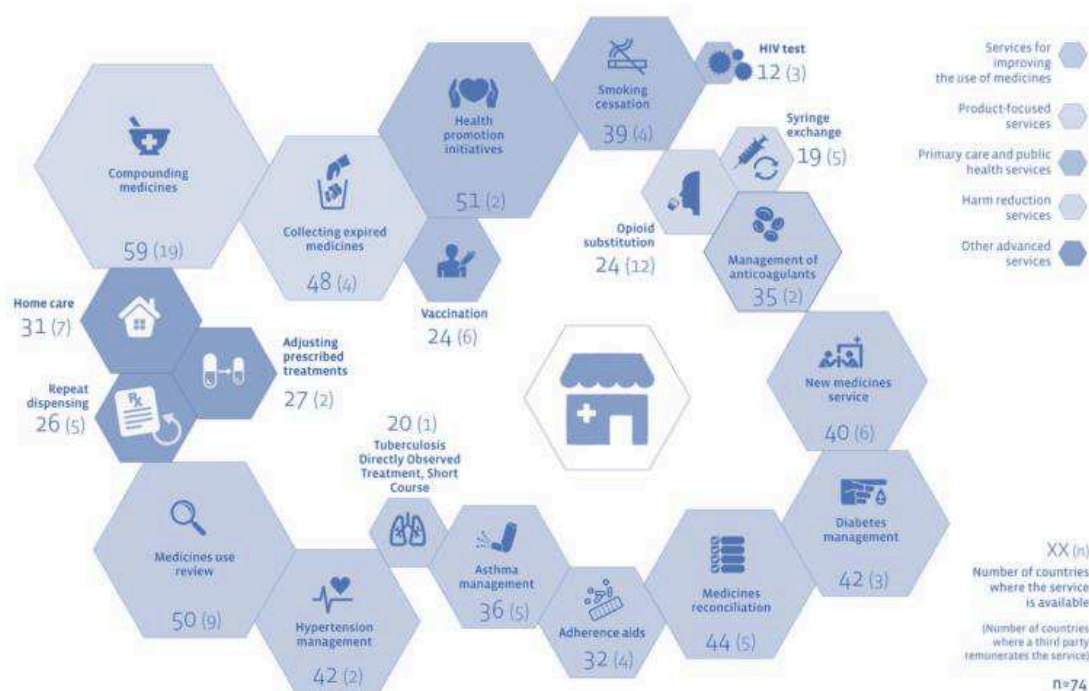


Figure 14 - Services available in community pharmacies across the world

Source: International pharmaceutical Federation - FIP, (2017)

Besides the medicines centred services that are delivery for most of the countries such as dispensing and counselling (n = 63) and compounding (n = 59) there are a number of advanced services being offered. Some of the advanced services are being provided in more than 50% of the countries like medicines use review (n = 50) and disease management programmes (hypertension or asthma) (n = 35) (International pharmaceutical Federation - FIP, 2017).

One of the services that is growing, and evolving is immunization. The availability of this service in community pharmacies increases accessibility, public vaccination rates and coverage as well as public acceptance, trust and support. Pharmacists are HCP really nearby to the population and can be actively involved with administration of vaccines (International pharmaceutical Federation - FIP, 2016a).

Some European countries are developing specific services and programmes in community pharmacies. The United Kingdom has been a pioneer implementing and integrating new services into daily practice. The services are integrated in the national health system and are developed across four key domains: medicines optimisation, self-care support; support a healthier life-style; support independent life-style. As part of the care plan, patients with long-term conditions benefit from the “Community Pharmacy Care Plan: The Patient Journey”, that provides assistance to the patients to achieve better outcomes and to help them manage the conditions

The NHS Community Pharmacy Contractual Framework (CPCF) enables community pharmacies that fulfil the requirements to choose to provide any of the six essential and advanced services. Among the advanced services are: Medicines Use Reviews (MURs), New Medicine Service (NMS) and Flu Vaccination (PSNC, 2013, 2014, 2017).

A systematic review performed by Melton & Lai, (2017) aimed to evaluate the pharmacist-led services and identify opportunities in the community pharmacy to improve patient satisfaction. Fifty studies were included in this review and the majority were pharmacy services implemented and defined as standard practice. The majority of the services is performed in countries that have some type of national health care, such as Australia, United Kingdom and Canada. In 32% of the studies a newly developed in-person service was described, apart for example from the information that is provided along with medicines dispensing. Most of these studies were related to medication and disease management, mostly in diabetes or asthma. Studies refer that community pharmacies in Australia are offering other services such as opioid substitution therapy and vaccination. Other studies found that community pharmacists' involvement in transitions of care reduce hospital readmissions. Generally speaking, the studies of

cognitive services have been well received by patients and this review demonstrates that patient satisfaction is improved when a pharmacist is involved in the patient journey through the healthcare system (Melton & Lai, 2017).

Recently in Portugal, a new statute defined five new services that can be available in community pharmacies, in addition to the eight already established by law since 2007 (Ministério da Saúde, 2007b, 2018). These new services include: nutrition counselling; adherence/compliance support, medicines reconciliation and medical devices educational programs; point-of-care testing for HIV, HCV and HBV; nursing services, namely wound care and stoma appliance; Level I care treatment for diabetic foot according to the legislation (Ministério da Saúde, 2018). Moreover, to provide these services, the community pharmacy should have the adequate facilities and trained pharmacists. The previous eight services defined by the statute from 2007 included health promotion, homecare support, first-aid, administration of medicines, use of auxiliary diagnostic and therapeutic means, administration of vaccines non-included in the national program of vaccination, pharmaceutical care programs, health screening, and collaboration in health education programs (Ministério da Saúde, 2007).

2.4.5 – Barriers and Facilitators

A vast body of literature identifies barriers and facilitators to the implementation and the sustainability of CPS (Cabrera *et al.*, 2005; Hossain *et al.*, 2017; Smith, Spiggle, & McConnell, 2016).

Barriers are obstacles that obstruct the dissemination, implementation and sustainability of CPS can be categorized into four types: situational barriers, that include working conditions; cognitive barriers, such as lack of knowledge or ability to perform the service; legal barriers, including regulations for the practice of pharmacy and attitudinal barriers, including pharmacists' beliefs about themselves, other health professionals, and patients. (Raisch, 1993; Roberts, Benrimoj, Chen, & Williams, 2006).

Facilitators of practice are factors that can facilitate progress. Facilitators are seen as crucial elements to support pharmacy and pharmacists in overcoming barriers (M. A. Gastelurrutia *et al.*, 2009).

In 2014 a Portuguese study aimed to assess pharmacists' perception about barriers for the implementation of advanced pharmaceutical services and to collect information about facilitators for this practice. This was performed by trying to implement medication review and dose administration aids to foster adherence in community pharmacies (Pedro, Miranda, & Costa, 2016).

The main barriers identified by pharmacists were concordant with several described by previous authors. These included: lack of remuneration, lack of time, lack of support from the main stakeholders, lack of education and training on advanced pharmaceutical services, lack of motivation among the pharmacy team and lack of cooperation between pharmacists and GPs. The pharmacists in the study also believed that services like those described could be implemented in the future, as long as barriers could be transformed into facilitators.

The barriers for dissemination, implementation, and sustainability of different cognitive services can be categorized into 6 areas: pharmacists (lack of education and training), community pharmacy (structure and business model), pharmacy profession (the lack of university clinical education), health authorities (lack of real involvement by health authorities), GPs (lack of interprofessional attitudes), patients (lack of demand of these services by patients). These barriers specially lack support staff, problems with consultation areas and also lack of investment in the pharmacy structure were identified when a group investigated factors that influence the implementation of Medicines use reviews (MURs). These barriers fit in with the barriers identified in other countries (M. Á. Gastelurrutia, Fernández-Llimos, Benrimoj, Castrillon, & Faus, 2007; Latif & Boardman, 2008)

In 1990, Hepler highlighted the need for reimbursing pharmaceutical care provision, and consequently lack of remuneration has been constantly described as one of the barriers to provide this service. However, many researchers and policy makers identified other barriers for the provision of services.

Roberts *et al.*, (2006) suggest that a number of barriers and facilitators are identified through the literature. However, once identified, it is difficult to perceive how these can be used in practice to implement and develop new CPS (Table 3). The study

suggests that changes should start on the organizational level, by identifying facilitators in this dimension (Roberts *et al.*, 2006).

Table 3 - Barriers and Facilitators in pharmacy practice

Source: Adapted from Roberts *et al.*, (2006)

Barriers

- Pharmacist-related
 - Attitude (lack of confidence)
 - Practice skills (limited communication skills)
- Resource-related (lack of management, protocols and guidelines)
- System-related
- Academic and education related (Knowledge and training)
- Other (lack of vision, mentors)

Facilitators

- Individual
 - Pharmacist competence; motivation; communication skill; leadership skills; professional satisfaction; pharmacists' attitudes towards CPS
- Organisational
 - Remuneration; HCP relations; use of pharmacy technicians; culture of the pharmacy; Adequate space and room

Another study, conducted by Roberts *et al.*, (2008) aimed to quantify facilitators of practice change in Australian community pharmacies. The study was based on real pharmacist experience and implemented services in the community pharmacies. Some specific facilitators were identified such as: relationship with other HCP, remuneration, pharmacy facilities, patient expectation, pharmacy members, communication and team work and support from outside entities. This results strengthens the idea that the implementation of new services should be part of a bigger strategic plan that includes all the elements described (Roberts *et al.*, 2008)

An important point of view is that pharmacists can by themselves be a barrier for the application of new CPS. In Canada, M. Rosenthal, Austin, & Tsuyuki, (2010) question the pharmacists' culture and if pharmacists themselves are prepared for a practice change. They identify lack of confidence, fear of new responsibilities, need for approval, the fact that pharmacists often underrate their performance as barriers to this change. They suggest that there is room for improvement, starting by understanding their own pharmacist's culture and embrace new challenges (M. Rosenthal *et al.*, 2010).

The relationship with the physicians has been identified as one of the major facilitators in previous studies. A study in 2017 conducted by Hossain *et al.*, synthesized the elements that are identified to be barriers and facilitators in daily practice. In this study 63 elements were identified influencing CPS implementation. These elements were classified into 4 categories. This study showed that an element can be seen as a barrier or as a facilitator from different professionals' perspectives. This study is also a great example of the interprofessional collaboration that has been evolving through the years and that has a major impact on the patient-centred approach. (Hossain *et al.*, 2017).

2.4.6 – Medication Review

Medication review (MR) is a multifaceted intervention provided across a range of different setting. Furthermore, it is known that community pharmacists can engage in a positive role by identifying drug related problems (DRPs) in patients and therefore decrease the risk for drug-related errors by providing this service (Jokanovic *et al.*, 2017; Kwint, Faber, Gussekloo, & Bouvy, 2011).

The PCNE issued a position paper in 2016 where MR was defined as “a structured evaluation of a patients' medicines with the aim of optimising medicines use and improving health outcomes. This entails detecting drug related problems and recommending interventions.” (Pharmaceutical Care Network Europe, 2016).

Furthermore, the PCNE developed a typology for MR according to the information available for pharmacists to engage in the evaluation of patient's medication. Three levels (simple, intermediate, advanced) of medication reviews are described, which can be further broken down into four different types (1, 2a, 2b, 3)

Table 4 - PCNE Typology of MR.

Source: Pharmaceutical Care Network Europe, (2013)

Characterisation		Information available		
Type	Level	Medication history	Patient interview	Clinical Data
Type 1	Simple	✓		
Type 2a	Intermediate	✓	✓	
Type 2b		✓		✓
Type 3	Advanced	✓	✓	✓

In 2017, the PGEU reported type 1 MR to be available in 30 European countries (100% of those surveyed) and type 2 available in 17 countries. However, there are different designations across the countries such as: Medicines Use Reviews in the UK, Polymedication check in Switzerland, Pharmacotherapy Review in Slovenia or pharmacotherapy follow-up in Spain, they all resume in a cognitive service that assesses patient's medication and aims to optimise the drug-related problems and improve health outcomes (Hersberger & Messerli, 2016; Pharmaceutical Group of the European Union, 2017b; PSNC, 2015; F. van Mil & Schulz, 2006).

In fact, Bulajeva *et al.* in 2011, described that 14 out of 25 European countries were providing at least one type of MR. This proportion is much lower, even considering that it reports to six years before, leading to suspect the consistency of information collected by different bodies and using distinct methods. Bulajeva and colleagues also highlighted in this paper that at the time there was limited access to patient information, leading to varying quality of MR provided across Europe (Bulajeva *et al.*, 2014).

There is evidence on the impact of medication review on patient's health. A systematic review undertaken by Jekanovic *et al.*, (2017) including 35 studies on pharmacist-led medication review in the community setting identified positive clinical outcomes. The most commonly reported outcomes evidencing improvement were diabetes control, blood pressure control and cholesterol values.

Pharmacist-led medication reviews performed in daily practice showed to reduce hospitalization by 5.84% comparing with patients treated with usual care (Hatah, Braund, Tordoff, & Duffull, 2014).

Results and outcomes of these interventions have also been described using cost-effectiveness and cost-utility studies.

A study comparing the benefits to polypharmacy patients of medication review with follow-up (MRF) with usual care showed decreased costs to the NHS. These results suggest that there might be room for payment from the NHS in order to cost-effectively improve the healthcare system. The cost analysis showed that the MRF saved 97 € per patient in 6 months. Likewise, a study for the same service proved to be an effective intervention for medicines optimization, the outcomes of this cost-effectiveness analysis were measured in quality-adjusted life-years (QALYs), resulting in mean incremental QALY of 0.0156.

In Italy, medicines use review was the first cognitive service to be provided in community pharmacies. The study that assessed the cost-effectiveness of the service showed that the probability that Italian medicines use review (I-MUR) was more cost-effective is 71.50% in asthma control and adherence to treatment after I-MUR. The service was effective and cost-effective and for this reason it was the first service being funded by the government (Manfrin *et al.*, 2017). These studies suggest that real-world evidence may be used to demonstrate the potential effectiveness and cost-effectiveness of CPS or other pharmacists' interventions (Jódar-Sánchez *et al.*, 2015; Malet-Larrea *et al.*, 2017; Manfrin *et al.*, 2017).

2.5 – Remuneration Models

Health care systems are financed through a number of financing schemes. Depending on the countries health spending, these can be distributed by government schemes, health insurance (compulsory or voluntary), out-of-pocket or other manners. In the majority of the EU, government structures and health insurance conjointly are the most common health care financing measures (Figure 15) (OECD/European Observatory on Health Systems and Policies, 2016).

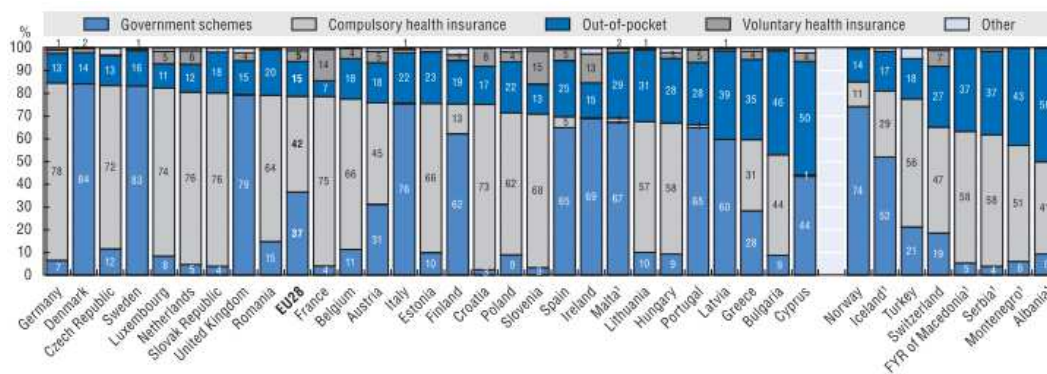


Figure 15 - Health expenditure by type of financing

Source: (OECD/European Observatory on Health Systems and Policies, 2016)

CPS integration into the professional practice and business model of a community pharmacy is increasing. One of the reasons for this change is the economic pressure into the traditional pharmacy business model (Farris *et al.*, 2006). Internationally, there is a new trend for governments, health insurances corporations and patients, to pay for a range

of services in the community pharmacies designed to improve patients' health outcomes (Chan *et al.*, 2008).

Previous research has suggested that the viability of pharmacy services depends heavily on the remuneration models in place, mainly because the pharmacy structure is a small to medium enterprise which must ensure return on its investments. Implementing a new service has associated costs, which include the staff, the training and material resources, to name a few. To cover these costs, the services need to be charged and the payer may be the patient, the government or the health insurer (Latif & Boardman, 2008; Roberts *et al.*, 2008).

Although the provision level of the services is increasing, pharmacists keep mentioning the lack of incentives for pharmacists to develop and implement new CPS (Roberts *et al.*, 2006). The absence of remuneration has also been pointed out by the patient as reason to be poorly adherent and to be dissatisfied with the services (Hashemi-Meshkini, Keshavarz, & Nikfar, 2013). According to Houle *et al.*, remuneration occurs when the cost of the service, provided by the pharmacy (or pharmacist), is supported by the government or insurance companies, therefore excluding the out-of-pocket payments by the patient from this definition of remuneration (Houle, Grindrod, Chatterley, & Tsuyuki, 2014).

In 2015, the FIP surveyed 34 countries about the remuneration models in community pharmacies and discussed the sustainability of pharmacy services. In most of the countries involved, the costs of the community pharmacy are assigned to the medicines dispensing but also to pharmacist-led cognitive services such as point-of-care testing or vaccination. The remuneration components are based in three main categories: product-based (margin and add-on per product); structure (fee on duty, capitation fee and fee for structure); and activities (fee for service). This report suggested pharmacy remuneration systems could be improved by adding more reimbursable services. However, in order for this to happen, the remuneration models must be created between pharmacies and the society. The payments for the additional services must comprise incentives for the sustainability and for the implementation of new services (International pharmaceutical Federation - FIP, 2015).

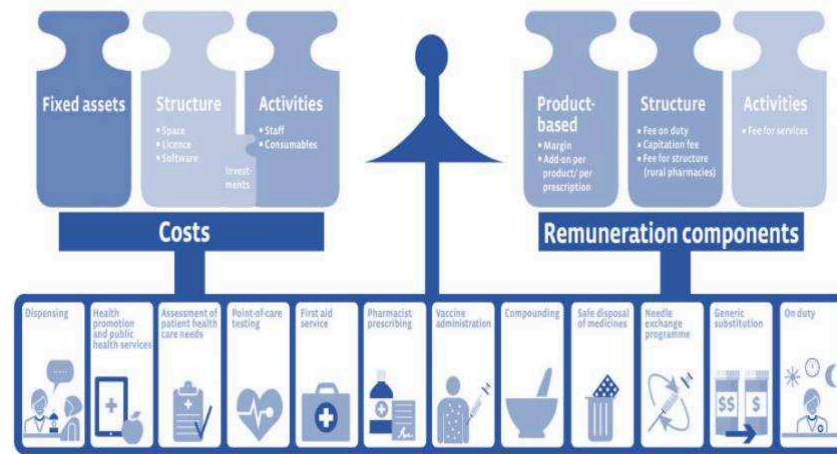


Figure 16 -.Components of the remuneration model for community pharmacies

Source: International pharmaceutical Federation - (FIP, 2015)

Some countries have had services remunerated for quite some time. However, the number of countries with structured reimbursement systems is still quite limited. An updated report issued by FIP in 2017 stated that the most common remuneration model relies on costs being supported by the community pharmacy or the patient, suggesting room for improvement.

This conclusion is consistent with previous literature, stating that most of the associated costs are being covered by the patient and only 12% of the service costs are being covered by public or private health insurances (Bulajeva *et al.*, 2014; International pharmaceutical Federation - FIP, 2017)

Sustainability of existing services and implementation of new services requires continuous professional development of the pharmacy staff (pharmacists and technicians) to ensure adequate competencies for quality service provision are in place. Occasionally, the healthcare professional cannot take over all these costs, so there is a need for the pharmacist to engage with the patient to ensure the best possible care. In this case there's a necessity to evaluate the patients' willingness to pay for the service (Kaae, Sondergaard, Haugbolle, & Traulsen, 2010).

Very few studies address the consumer's perspective of the value of the services and fail to evaluate the willingness of consumers to pay for a service. A systematic review assessed the patients' view on this subject, concluding that willingness to pay is influenced by socio-demographic variables or by the dichotomy between increased disease severity and prevention of medication-related problems. It has been suggested that pharmaceutical care, and counselling focused on medication-related problems are

both services that patients are willing to pay (Larson, 2000; Painter, Gressler, Kathe, Slabaugh, & Blumenschein, 2018).

Having a third-party payer may be seen as a form of recognition of the value of the service and may in theory lead to greater service uptake by patients and increased patient satisfaction (Bulajeva *et al.*, 2014; Hashemi-Meshkini *et al.*, 2013).

The existing remuneration models used in healthcare are well established. Some of the most common forms of remuneration include the fee for service (FFS), pay-for-performance (P4P) and mixed models (MM). FFS is a retrospective activity-based payment, where billing is made based on individual services provided and patient contacts made. P4P is based on the principle that payment is made when there are objective indicators demonstrating a positive impact of service provision. There are also MM, which result from the combination of the previous models (Houle & Charrois, 2016; OECD Health Policies Studies, 2016; M. M. Rosenthal, Desai, & Houle, 2017).

In 2012, a systematic review was performed aiming to identify remunerated clinical pharmacy services and investigate the associated outcomes. Sixty remunerated services were identified across Europe and other countries such as Canada and Australia. The programmes were remunerated by the governments or by private insurance plans (Houle *et al.*, 2014).

FFS appears as the most common way of payment of cognitive pharmacy services. However, new trends are arising, namely payments based on the HCP's performance or in a model embracing the two previous. Between 2009 and 2013 Houle *et al.*, aimed to determine if there was a reduction in the blood pressure in different patients whose pharmacists were paid by P4P or FFS. Data points to a decrease in the magnitude observed in blood pressure when the pharmacist provided the service; however, there is no noticeable difference in the blood pressure values when pharmacists were paid by P4P or by FFS. The authors also consider that policy-makers should take into account that most pharmacists are usually paid by a fixed salary and may therefore not immediately be able to respond to the implementation of a P4P offering (Houle & Charrois, 2016).

Remuneration for cognitive services must be carefully designed to achieve the intended outcomes. The pay-for-performance model for example may include incentives such as judging the impact of professional development, which may lead to job-related stress or impact negatively on motivation. The results of the previous study suggest that a sudden or broad movement towards a P4P model can disturb the system and be faced

with resistance while a phased-in approach with a mixed model between FFS and P4P payment methods can have positive impacts in maintaining good relationship with other HCP and patients (Houle *et al.*, 2016).

There has been an evolution towards the remuneration of services. Table 5 provides an overview of the pharmacist's cognitive services provided in community pharmacies across Europe that are described publicly as being remunerated.

Table 5 - Pharmacist remunerated programs in Europe

Source: Adapted from (Deloitte Access Economic, 2016; Houle *et al.*, 2014; Ministério da Saúde; Associação Nacional de Farmácias, 2014; PCNE Wiki, 2015; PSNC, 2013)

Location	Service	Payer	Fee
Denmark	Inhaler Technique Assessment Service	Danish Ministry of Health	8.62€
The Netherlands	Medication Review Type 3	Insurance	35-75€ per MR
United Kingdom (Scotland)	Smoking cessation counselling	NHS Greater Glasgow & Clyde	5.67€ - 15.88€ depending on number of visits
United Kingdom (Scotland)	Heart failure service	NHS Scotland	41.9€ for initial review, 11.9€ per follow-up
United Kingdom (Scotland, England, Wales)	Medicines use review	NHS	31.93€ per MUR
United Kingdom (Wales)	Discharges medicines review	NHS Scotland	41.9€ per visit
United Kingdom (England)	Minor ailments consultation	NHS	3.4-7.94€
United Kingdom (Northern Ireland)	Minor ailments consultation	Health and Social care in NI	11.39€ for the first 500 consultations per pharmacy, 9.11 for next 1000 and 7.42€ after that
United Kingdom (England)	Appliance use review	NHS	31.93€ for an AUR conducted on pharmacy; 61.5€ for an AUR conducted at patients' home
United Kingdom (England)	New medication service consultation	NHS	22.81€ and 31.93€ for each completed NMS
United Kingdom (England)	Stoma Appliance Customisation (SAC)	NHS	1.14€ per item
Portugal	Generic substitution	NHS	0.35€ per box
Portugal	Needle exchange programme	NHS	2.4€ per exchange kit
Spain	Methadone services	NHS	€45 per month per patient
Switzerland	Polymedications Check	Swiss Federal Office of Public Health	45€
Switzerland	Dose Administration Aid system	Swiss Federal Office of Public Health	20€ per week

*To facilitate comparison, the remuneration amounts in GBP were converted to EUR using the conversation rates of Bank of Portugal of 30th May 2018

Chapter 3 – Methodology

I – Literature Review

3.1 – PICOS Strategy

The first stage of any research project should be an efficient review of published literature. That stage is essential to discover what is known about the topic, what is still unknown and what the controversial areas are. Finding out at an initial stage that there is nothing published about a given research topic can mean that is an extremely innovative and relevant topic or that the literature review was not systematic and merely a “browsing exercise”. The **PICOS** strategy was developed to effectively define a search strategy that addresses the essential aspects that reflect the key question. The PICOS strategy is represented by the following components: **P**opulation, **I**ntervention, **C**omparison, **O**utcomes, **S**tudy Design. In this study, this strategy was used, first by identifying all the keywords that may alternatively be used to describe each of the five components mentioned.

Research Question: How is the European panorama regarding Pharmacist-led Cognitive Services performed in primary care?

It is commonly accepted that three of the five components are sufficient to define an efficient search strategy, mostly in less researched areas. Using three components of this search strategy (**PIO**) and according to the research question, the key words in English were defined according to the Medical Subject Headings (MeSH) terms defined by the US National Library of Medicine, National Institutes of Health. This literature search was conducted using the PubMed and Google Scholar data bases, which covers papers from year 2000 and was finalised on 30th May 2018. Titles were initially screened, and abstracts were kept for all of those considered relevant. Abstracts kept were analysed and full text articles of potential hits were retrieved for critical analysis.

The keywords used in the search strategy were:

- **(P) Population:** pharmacist [MeSH term]
- **(I) Intervention:** (((((((((((((((((((community pharmacy services [MeSH term])) OR Point-of-Care Testing [MeSH term])) OR Immunization [MeSH term])) OR

- Pharmaceutical Care [MeSH term]) OR Medication Adherence [MeSH term])
 OR Drug Substitution [MeSH term]) OR Consumer Health Information [MeSH
 term]) OR Intravenous Administration [MeSH term]) OR Administration,
 Intranasal [MeSH term]) OR Homes for the Aged [MeSH term]) OR Emergency
 Contraception [MeSH term]) OR Drug Prescriptions [MeSH term]) OR Travel
 Medicine [MeSH term]) OR Smoking Cessation [MeSH term]) OR
 Pharmacogenomic Testing [MeSH term]) OR Mass Screening [MeSH term]) OR
 Early Detection of Cancer [MeSH term]) OR Needle-Exchange Programs [MeSH
 term]) OR Opiate Substitution Treatment [MeSH term]) OR Drug Utilization
 [MeSH term]) OR Anticoagulants [MeSH term]) OR Prothrombin Time [MeSH
 term]) OR HIV Core Protein p24 [MeSH term]
- **(O) Outcomes:** (((((((((((Prescription fees [Mesh term]) OR Fee-for-Service
 Plans [Mesh term]) OR Insurance, Health, Reimbursement [Mesh term]) OR
 Reimbursement Mechanisms [Mesh term]) OR Out-of-Pocket Payments [Mesh
 term]) OR Third-Party Payments [Mesh term]) OR Fees, Pharmaceutical [Mesh
 term]) OR Capitation Fee [Mesh term]) OR Fee Schedules [Mesh term]) OR
 Remuneration [Mesh term]) OR Direct Service Costs [Mesh term]) OR Cost-
 Benefit Analysis [Mesh term]) OR Cost Sharing [Mesh term]) OR (Costs and
 Cost Analysis [Mesh term])

The search combinations used applied in the search:

(pharmacist [MeSH term] AND community pharmacy services [MeSH term]) OR
 Point-of-Care Testing [MeSH term]) OR Immunization [MeSH term]) OR
 Pharmaceutical Care [MeSH term]) OR Medication Adherence [MeSH term]) OR
 Drug Substitution [MeSH term]) OR Consumer Health Information [MeSH term])
 OR Intravenous Administration [MeSH term]) OR Administration, Intranasal
 [MeSH term]) OR Homes for the Aged [MeSH term]) OR Emergency
 Contraception [MeSH term]) OR Drug Prescriptions [MeSH term]) OR Travel
 Medicine [MeSH term]) OR Smoking Cessation [MeSH term]) OR
 Pharmacogenomic Testing [MeSH term]) OR Mass Screening [MeSH term]) OR
 Early Detection of Cancer [MeSH term]) OR Needle-Exchange Programs [MeSH
 term]) OR Opiate Substitution Treatment [MeSH term]) OR Drug Utilization
 [MeSH term]) OR Anticoagulants [MeSH term]) OR Prothrombin Time [MeSH

term]) OR HIV Core Protein p24 [MeSH term]) AND (Pharmacists [Mesh Term]) AND (((((((((((Prescription fees [Mesh term]) OR Fee-for-Service Plans [Mesh term]) OR Insurance, Health, Reimbursement [Mesh term]) OR Reimbursement Mechanisms [Mesh term]) OR Out-of-Pocket Payments [Mesh term]) OR Third-Party Payments [Mesh term]) OR Fees, Pharmaceutical [Mesh term]) OR Capitation Fee [Mesh term]) OR Fee Schedules [Mesh term]) OR Remuneration [Mesh term]) OR Direct Service Costs [Mesh term]) OR Cost-Benefit Analysis [Mesh term]) OR Cost Sharing [Mesh term]) OR (Costs and Cost Analysis [Mesh term])).

A secondary literature search was used to complement the identified records. This search was divided into two sections:

- 1) Reviewing of the references used in retrieved articles from primary literature search, which were screened for relevant cross-referenced articles.
- 2) Searching specific databases purposefully chosen, either due to the characteristics of studies included (*e.g.* Cochrane, which focuses on high quality systematic reviews), or due to the type of data included (*e.g.* OECD - Organisation for Economic Co-operation and Development; which focuses on statistical data concerning the healthcare provision across Europa)

After the conduction of both primary and secondary searches and their combinations, duplicates were eliminated prior to detailed analysis.

The literature review results are presented in the section 4.1., resorting to PRISMA flow diagram (see Figure 17).

II – Research Project

3.2 – Study Design and study period

A two-phased cross-sectional study was conducted between November 2016 and October 2017. The first phase consisted of a cross-sectional study using an online survey (November 2016-March 2017). The second phase aimed at data validation and consensus seeking (April-October 2017).

This study is part of a larger project with two distinguished sections. First, an overview on different pharmacist-led cognitive services, and secondly (published separately as part of a PhD project from a colleague based at the University of Basel), a focus on the provision of different types of medication review (MR) (1,2a,2b,3) (Pharmaceutical Care Network Europe, 2016).

3.3 – Sample

The survey was sent to a purposive sample of 141 individuals from 44 different European countries part of the WHO Regional office for Europe. Participants were identified through the PCNE, the European Society of Clinical Pharmacy (ESCP), FIP, PGEU members' lists and further contacts from the project team.

In each country/region the survey was sent to a key representative that suggested two further participants. The criteria to select the three representatives aimed to ensure different and complimentary views of practice, by choosing three backgrounds for data triangulation: community pharmacy, pharmacy practice research and health policy.

3.4 – Design and content validity of the survey

A specific questionnaire was developed based on previous literature review and work by our group (Martins *et al.*, 2015), enriched with a search on official government websites, the PCNE Wiki - (<http://euopharm.pbworks.com/w/page/19341636/FrontPage>) and arising links.

To ensure all participants had the same understanding of the services explored (J. W. F. van Mil & Henman, 2016), the questionnaire included a list of definitions for the 22 PLCS [see additional file 1]. Whenever no MeSH term was available we have opted for the most robust and recently published study on that topic and adopted its definition. The concept of remuneration was as defined by Houle and explained in the survey with clear

instructions so that out-of-pocket payments were not considered (Houle *et al.*, 2014),(Houle & Charrois, 2016). For each service listed, we questioned the respondent on three domains: availability of the service, rate of implementation and existence of remuneration. The questions were phrased as:

1. Do you have the service 'xy' available in community pharmacies in your country (performed or supervised by a pharmacist)?
2. What is approximate proportion of pharmacies providing the service (%)?
3. How much does the pharmacy receive for this service in Euro (€)?

This survey was tested for content, format and wording with an expert panel of five individuals. This face and content validation resulted in a second version, then validated with an extended panel of eight experts.

3.5 – Data validation and consensus seeking procedure for the results obtained

Data triangulation was ensured using a consensus technique within the respondents from each country/region.

Countries/regions were segmented in three groups according to the number of respondents obtained:

Group A: countries/regions with 1 respondent;

Group B: countries/regions with 2 respondents;

Group C: countries/regions with 3 respondents.

An initial clarification step was used holding a face-to-face meeting in one of the countries where three respondents were obtained. This meeting aimed at obtaining in-depth knowledge of the possible reasons for discrepancies detected. Examples of cues arising were the data sources used, especially for the implementation rate and remuneration values quoted. Such exploration enabled the preparation of consensus documents for the remaining countries to seek long-distance clarification and subsequent data validation. As a result, the consensus document included two main questions: 1. State if the given answer was an estimate or if it arose from a valid source; 2. (if from a valid source) Provide references/ data sources.

In group A, the document was sent to a further person from the same country/region, who acted as a validator of the responses obtained by the sole responder.

In groups B and C, a consensus document was developed and resent to the same participants, informing them of the previous responses obtained and asking them to rethink their answers aiming for consensus. The ultimate goal for all three groups was to agree on a unified answer within the country/region.

Unified data were then categorized into three grades of validation so that readers are clear on the strength of evidence:

- full validation (validated by all participants or by the majority);
- partial validation (validated by one participant);
- no validation (no participant validated this information).

Regardless of the validation group, additional external agreement was sought using official documents publicly available. These were used to evaluate the credibility of our results, by comparing and contrasting with the information received from participants.

3.6 – Data Analysis

Data were collected using the online Findmind© tool, allowing extraction to Microsoft Excel 2016, where the descriptive analysis was performed. Worldwide, pharmacies dispense medicines and as such, all PLCS were reported to be provided either independently or as an integral part of medicines dispensing (*e.g.* provision of information upon dispensing). Independent provision was considered as a service that may be provided as an “add-on” to medicines dispensing, either provided at the same moment or on different occasions (*e.g.* inhalation technique or adherence support) or as a service that is provided totally separate from medicines dispensing, even when no dispensing is occurring (*e.g.* smoking cessation).

However, data on the rate of implementation and remuneration only concerns services provided independently. Three qualitative levels of implementation were considered by the research team to classify quantitative responses obtained: low (1-33%); medium (34-66%); high (67-100%). These cut-offs were defined purely based in mathematical reasoning and not based on any published reference, as there was none found.

Remuneration data are presented indicating the remuneration models: Fee-for-service (FFS), Pay-for-performance (P4P) and Mixed models (MM).

All these data are presented in three tables. Each table refers to the clustering of services, according to their complexity and demands by adopting the PGEU classification (2010) (Pharmaceutical Group of the European Union, 2010). This classification assumed there are:

- **Core Services:** essential services provided by all licensed pharmacies during core pharmacy opening hours.
- **Basic Services:** may require separate consultation facilities and special training of pharmacy staff; may need to be available outside core pharmacy opening hours (*e.g.* during the night)
- **Advanced Services:** require separate consultation facilities in the pharmacy and accredited pharmacists to provide it.

According to the PGEU definitions, the research team conducted a consensus technique to agree on the integration of each PLCS into one of the three categories.

For each section, data is analysed using descriptive univariate statistics, presented either by absolute and relative frequencies or by central tendency and dispersion measures, according to the nature of the variables concerned.

3.7 – Ethics approval and consent to participate

In this survey it was not possible to guarantee the anonymity, the questionnaire's filling was volunteer. By opening the questionnaire, the participant was consenting the confidential treatment for the answers, as aspect clearly presented ahead of the decision to proceed.

The Ethical approval for this study was obtained from “Comissão de Ética Egas Moniz” on 26th October 2016 (Proc. Number 515).

Chapter 4 – Results

The literature extracted from the literature review phase of the project is presented using the PRIMA Statement (**Error! Reference source not found.**). According to this diagram, we can see the number of exacted publications from each of the PIO sections of the review undertaken, as previously explained, followed the number of articles effectively screened and then those retrieved, which formed the basis of the body of literature used for this thesis.

I - Literature Review

4.1 – PRISMA Statement

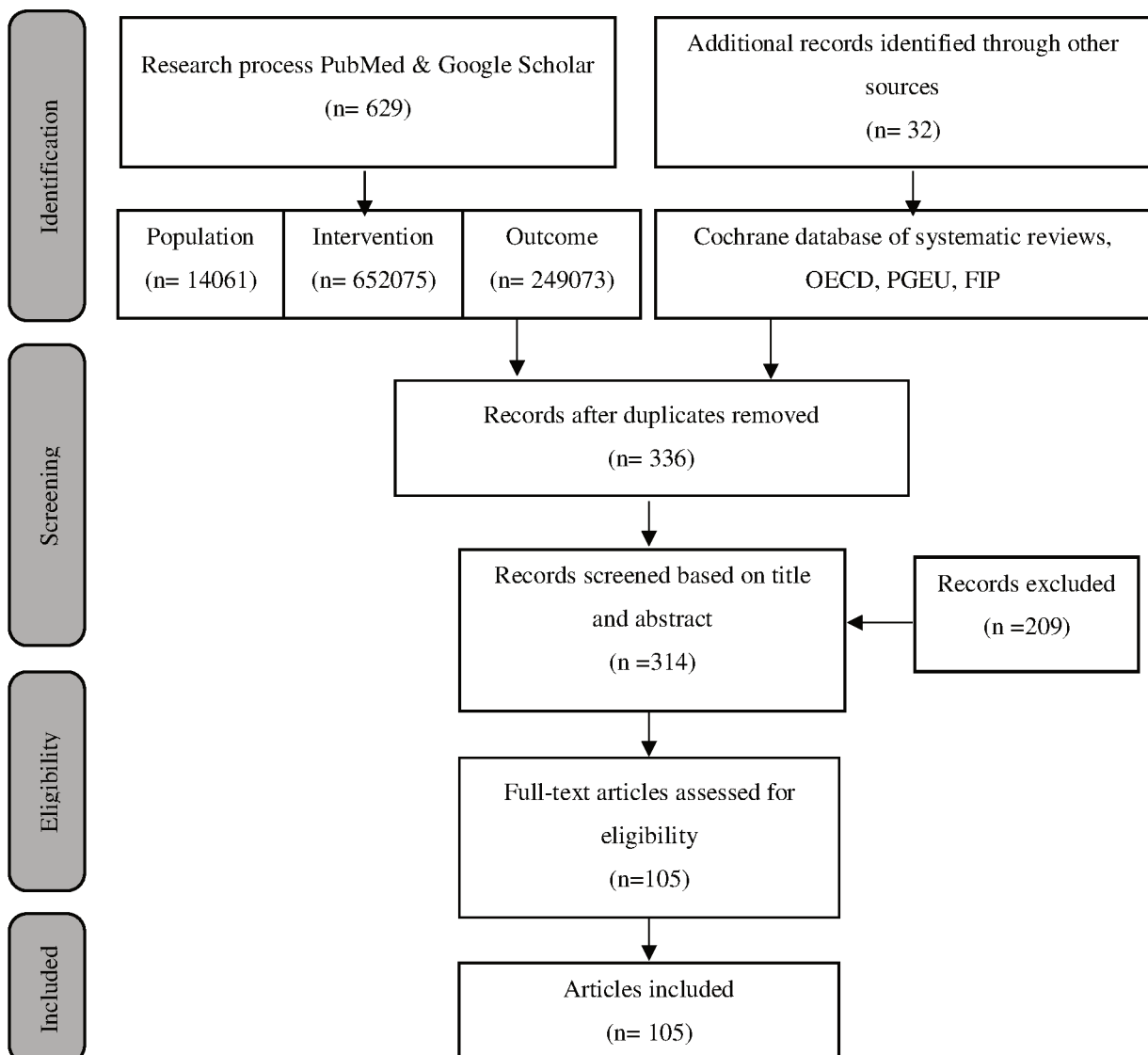


Figure 17 - Literature Review according to PRISMA 2009 Flow Diagram

Source: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009).

II – Research Project

4.2 – Sample Characterization

Contact persons in 44 European countries were approached, from the theoretical list of 48 countries (91.6%): Albania, Armenia, Austria, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, England, Estonia, Finland, France, Georgia, Germany, Hungary, Iceland, Ireland, Italy, Kosovo, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Moldova, Norway, Northern Ireland, Poland, Portugal, Romania, Slovakia, Scotland, Serbia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey, Ukraine and Wales. Of these, we obtained responses from 34 different countries/regions across Europe: Albania, Austria, Belgium, Bulgaria, Croatia, Denmark, England, Estonia, Finland, France, Georgia, Germany, Hungary, Iceland, Ireland, Kosovo, Latvia, Luxembourg, Macedonia, Malta, Norway, Northern Ireland, Poland, Portugal, Romania, Slovakia, Serbia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey and Ukraine with a 77.2% response rate. (Figure 18).

We had 15 countries/regions with three participants, 12 with two participants and 7 with one participant, with a mean value of 2.2 participants per country/region.

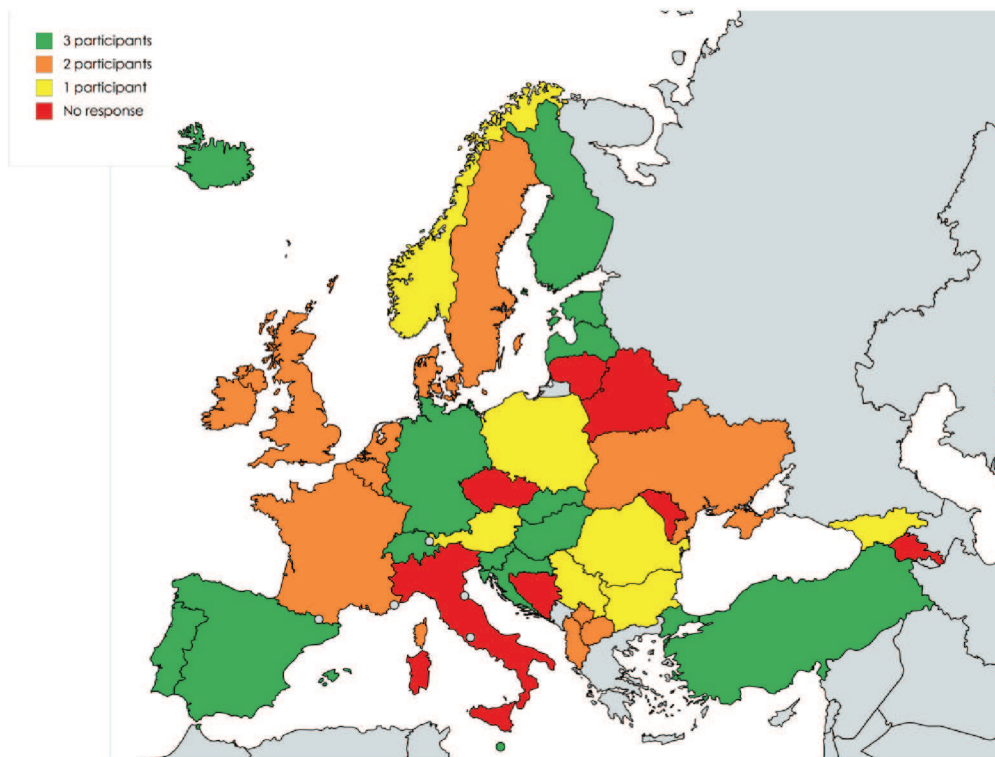


Figure 18 - Response Rate

We also had ten extra participants, who acted as validators in eight countries: England (n=1), Austria (n=2), Norway (n=3), Bulgaria (n=1), Poland (n=1), Romania (n=1) and Northern Ireland (n=1). Considering the entire pool of respondents, including the validators, the three areas of practice were quite evenly distributed (38.2% community pharmacists; 32.9% pharmacy practice researchers; and 28.9% health policy makers) (Figure 19).



Figure 19 - Areas of practice of the participants

Full validation was achieved for 25 countries/regions, meaning in these countries we had response from all validators or from the majority (73.5%); partial validation was obtained for six countries/regions, which implies one validator was obtained (17.6%); and no validation was possible for three countries/regions, which means in these countries there were no respondents found available to be used as validators (8.8%)(Figure 20).

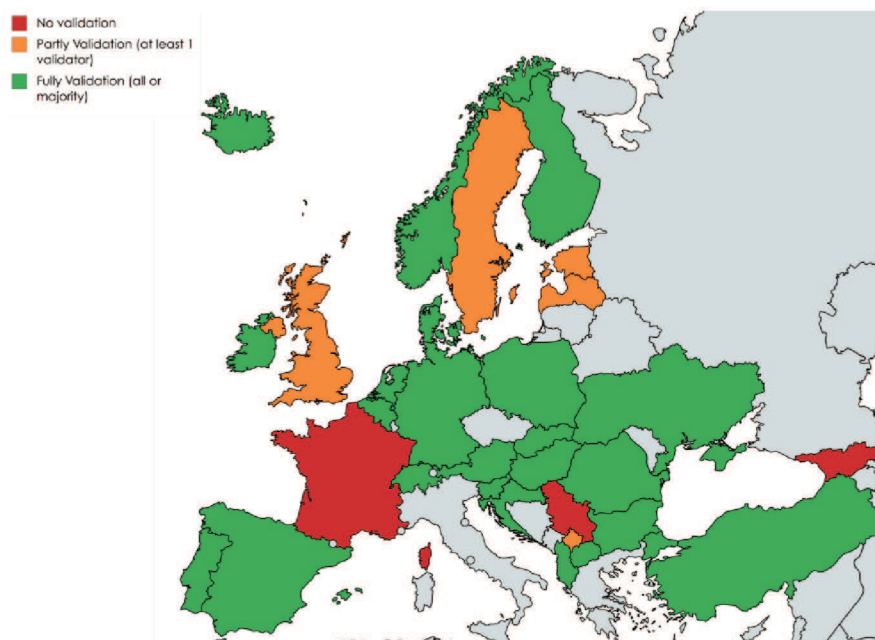


Figure 20 - Grade of Data Validation

4.3 – Pharmacist-led Cognitive Services

To have a better comprehension on the results, PLCS are presented with further details in three components: availability, level of implementation and remuneration models. Results are presented in tables below in the text and concern specific information about the countries and the three corresponding components.

4.3.1 – Availability

The data confirms all countries/regions provide medicine dispensing (100%, n=34). Data suggests that the five more commonly available services in European pharmacies are provision of medicine information (94.1%, n=32), generic substitution (85.3%, n=29), medication review (79.4%, n=27), provision of emergency oral contraception (70.6%, n=24) and point-of-care testing (67.7%, n=23). Conversely, the more seldomly provided seem to be personalized medicine (2.9%, n=1), prescribing (5.9%, n=2), administration of injectable medicines (5.9%, n=2) and INR testing and/or management (5.9%, n=2), (Figure 21).

Data suggests some countries have a wider scope of services available compared with the present sample of 22 PLCS, namely England and Portugal (81.8%, n=18), The Netherlands (72.7%, n=16) and then Switzerland, Austria, Belgium and Finland (63.6%, n=14). Countries/regions reporting to provide fewer services were Poland (9.1% n=2), Kosovo and Macedonia (13.6%, n=3), Turkey (18.2%, n=4) and Romania (22.7%, n=5), (Figure 22).

Generic substitution and provision of medicines' information are always provided as part of medicines dispensing. On the other hand, some services are exclusively provided independently in all countries/regions, namely administration of injectable medicines, immunization, INR testing and/or management, medication review, personalized medicine and prescribing. From those services provided independently, the most commonly provided were medication review (79.4%, n=27), health screening (38.2%, n=13), opioid substitution (38.2%, n=13), smoking cessation (35.3%, n=12), home delivery of medicines and assessment of inhalation technique (29.4%, n=10). Apart from the above mentioned in figure 26 as rarely provided, prescription renewal (8.8%, n=3) was also scarcely reported.

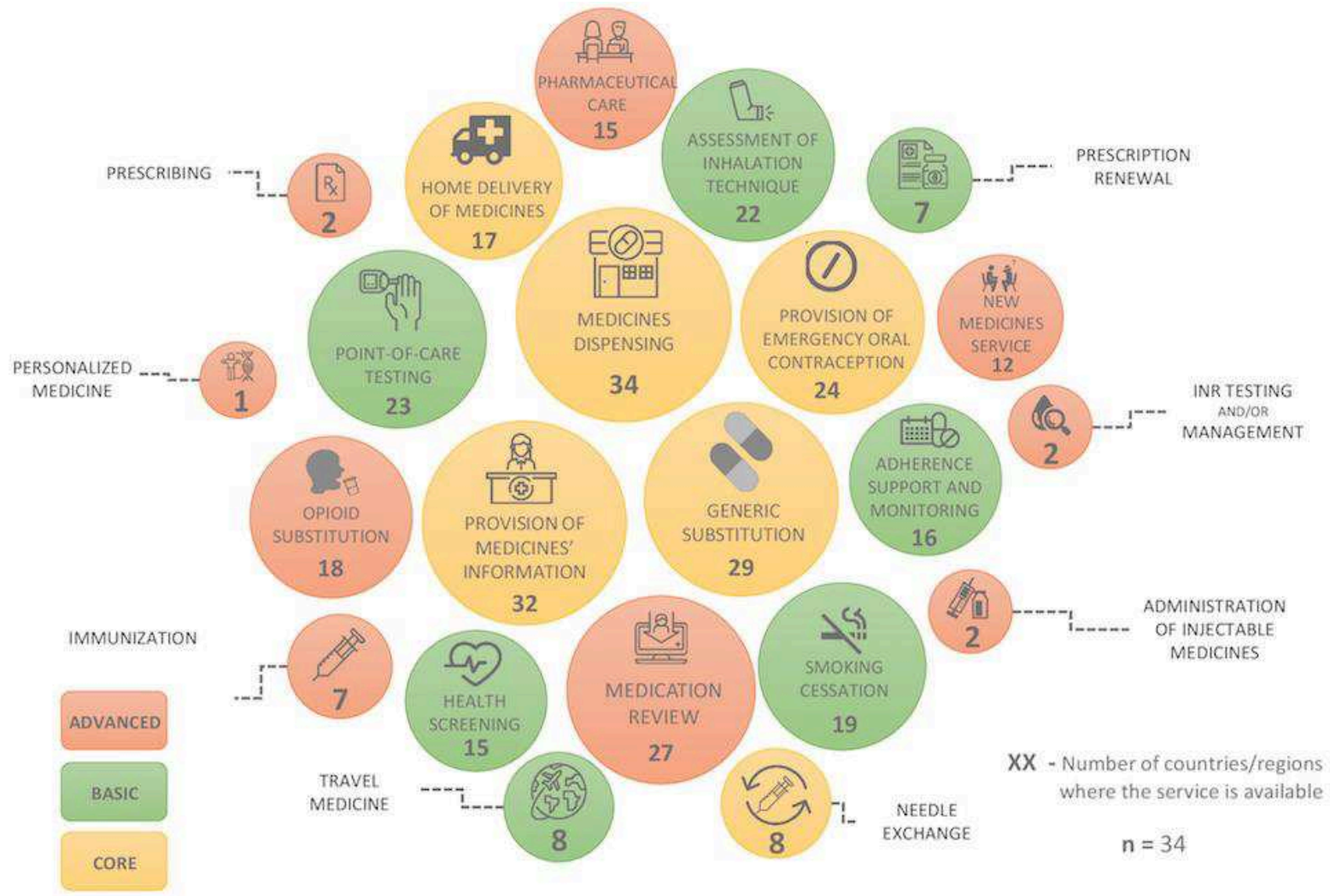


Figure 21 - PLCS available in primary care across Europe clustered into PCNE classification (2010)

XX - Number of pharmacist-led cognitive services provided across Europe

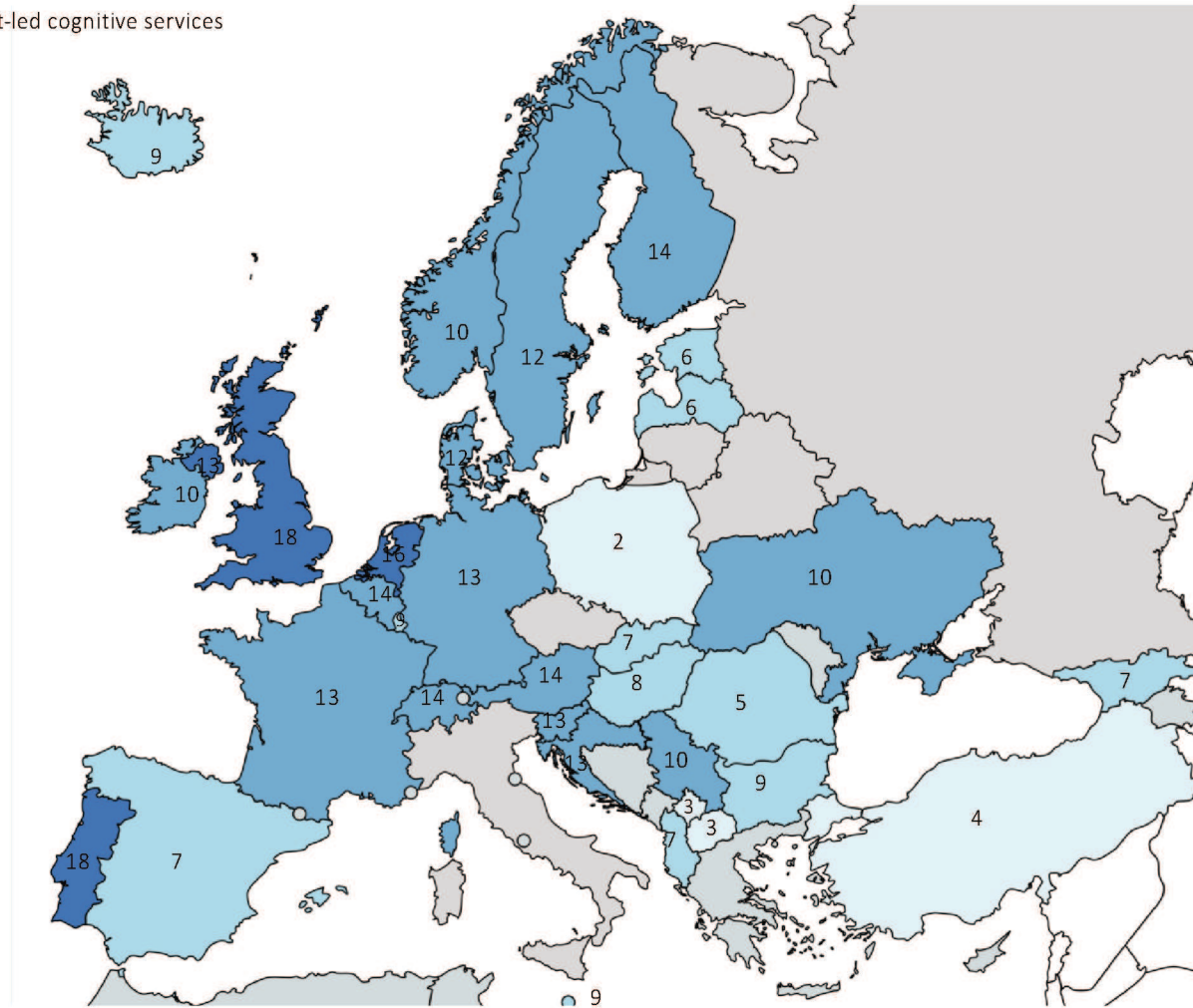


Figure 22 - Number of PLCS provided across Europe

4.3.2 – Implementation Level

The implementation level of at least one independent PLCS was reported by 24 countries/regions (92.3%) (Figure 23). Overall, levels of implementation were reported for 59.2% of the services.

From these services where data were obtained, the majority (52.8%) revealed low levels of implementation, a considerable proportion (37.1%) was found to have high levels of implementation and a minority (10.1%) reported medium level of implementation. The highest implementation rates were reported for medication review, adherence support and monitoring, prescription renewal, opioid substitution and travel medicine. The lowest implementation rates were reported for needle exchange, assessment of inhalation technique, smoking cessation, health screening and pharmaceutical care.

Overall, regardless of the specific service, the countries/regions where more services were reported as having high levels of implementation were Austria, Luxemburg, Northern Ireland, Norway, The Netherlands, England, Sweden and France.

On the contrary, some countries/regions consistently reported low levels of service provision, namely Belgium, Croatia, Denmark, Finland, Slovenia and Portugal (Figure 23).

4.3.3 – Remuneration Models

The majority of countries/regions (70.6%) described a remuneration model for medicines dispensing with one of the following components: mark-up, regressive margin, fixed fee, margin + fixed fee or capitation fee (Kanavos *et al.*, 2011; OECD Health Policies Studies, 2016).

Twenty-one countries provided details about their remuneration models on the independent PLCS (80.8%) (Figure 23). Some models of remuneration were mentioned in half the participating countries/regions: Austria, Belgium, Finland, Ireland, Luxemburg, Northern Ireland, Norway, Portugal, Switzerland, Slovenia, The Netherlands, England, and France. Countries/regions with a wider range of remunerated services were Northern Ireland (n=5; assessment of inhalation technique, smoking cessation, opioid substitution, immunization and prescribing); England (n=4; adherence support and monitoring, new medicines service, immunization and medication review); and Switzerland (n=3; adherence support and monitoring, opioid substitution, medication review).

In most countries/regions, remuneration models were predominantly based on a FFS. Examples include the adherence support monitoring, where reported rates may vary between 13 and 120€ per session or 45 to 80€ per month; opioid substitution with a co-payment of 5€ per dispensed item plus a monthly fee that varies between 30 and 100€ per month. Other services with lower remuneration rates include the new medicines service, with a compensation of 20-30€ per service (Belgium and England), immunization, compensated at 15€/vaccine in Ireland and 14€/flu vaccine in Northern Ireland and needle exchange change with a compensation of 2.4€ per exchange (Portugal). Services with a mixed model of remuneration include smoking cessation in Northern Ireland, new medicines service in England and medication review in Germany.

Data suggests an apparent trend between the existence of remuneration and high levels of implementation (Figure 23). This observation is supported by data on adherence support and monitoring in Austria and England; assessment of inhalation technique in Norway; smoking cessation in Northern Ireland; pharmaceutical care in Austria and The Netherlands; new medicines service in England and The Netherlands; immunization in England; prescribing in Northern Ireland; and medication review in Switzerland, The Netherlands and England.

The contrary is also true, where services with a low level of implementation are often unpaid by third parties. Examples comprise home delivery of medicines, assessment of inhalation technique and pharmaceutical care in Portugal and Slovenia; needle exchange in Spain; adherence support and monitoring in Finland and Portugal; smoking cessation in Croatia, Finland, Portugal, Slovenia, Ukraine and Serbia; health screening in Croatia, Finland, Slovenia and Estonia; travel medicine, new medicines service, administration of injectable medicines and INR testing and/or monitoring in Portugal; immunization in Denmark; medication review in Croatia, Denmark, Hungary, Portugal and Ukraine.

There are obviously exceptions to this trend, where services with low implementation levels are remunerated, such as needle exchange in Ireland; new medicines service for asthma in Belgium; immunization in Northern Ireland and medication review in Germany and Slovenia; and services with high implementation levels and not being paid by third parties, such as immunization in Portugal and prescription renewal in Finland, Northern Ireland and The Netherlands.

Seemingly, there is an observable geographic pattern in Figure 23, relating the implementation level and the remuneration model of each PLCS in the different European regions. In the Southern region, Portugal (POR) and Spain (ESP) are highlighted by a red spot, representing low implementation of PLCS and non-remuneration for most PLCS. However, there might be variability between different regions in Spain that are not described in this study, pointing for the local provision of some services, some of them also remunerated, namely in the Catalonia region or the Basque Country. Conversely, point-of-care testing and immunization are being provided to a high extent in Portugal, although both are non-remunerated, the exception being the existence of a fee-for-service provided by the National Health System for the needle exchange in Portugal.

In the Western region, Austria (AUS), Germany (DEU), France (FRA), Ireland (IRL), Belgium (BEL), The Netherlands (NLD), England (ENG), Northern Ireland (NI), and Switzerland (CHE), the trend seems to be more positive in levels of implementation, with high levels of implementation represented by the green colour. Additionally, most of the services are remunerated using a fee-for-service model.

In the Northern region, Estonia (EST), Sweden (SWE), Norway (NOR), Denmark (DNK) and Finland (FIN), the panorama changes and the services are provided but in the lowest level of implementation, only 1-33% of the community pharmacies are providing the service on a daily basis. Finland is the exception for medication review and prescription renewal with high implementation rates. Norway is the only country in this region providing a remunerated service, assessment of inhalation technique with a fee for service. In the Eastern region, Slovakia (SKV), Serbia (SRB), Hungary (HUN), Ukraine (UKR), Slovenia (SVN) and Croatia (HRV) the red colour indicates all the services are provided with the lowest implementation level, except for Slovenia and Ukraine. Slovenia is providing provision of emergency oral contraception and assessment of inhalation technique in 67-100% of the community pharmacies and Ukraine provides home delivery of medicines in 34-66% of the community pharmacies and health screening in 67-100% of the community pharmacies. Slovenia also is the unique country surveyed where a pay-for-performance model was reported, and this was for the provision of medication review. Data suggests that the Western European region has a higher availability of PLCS than Southern, Northern and Eastern Regions. Furthermore, there are more co-payments by the NHS or health insurers in this region comparing to the rest of Europe.

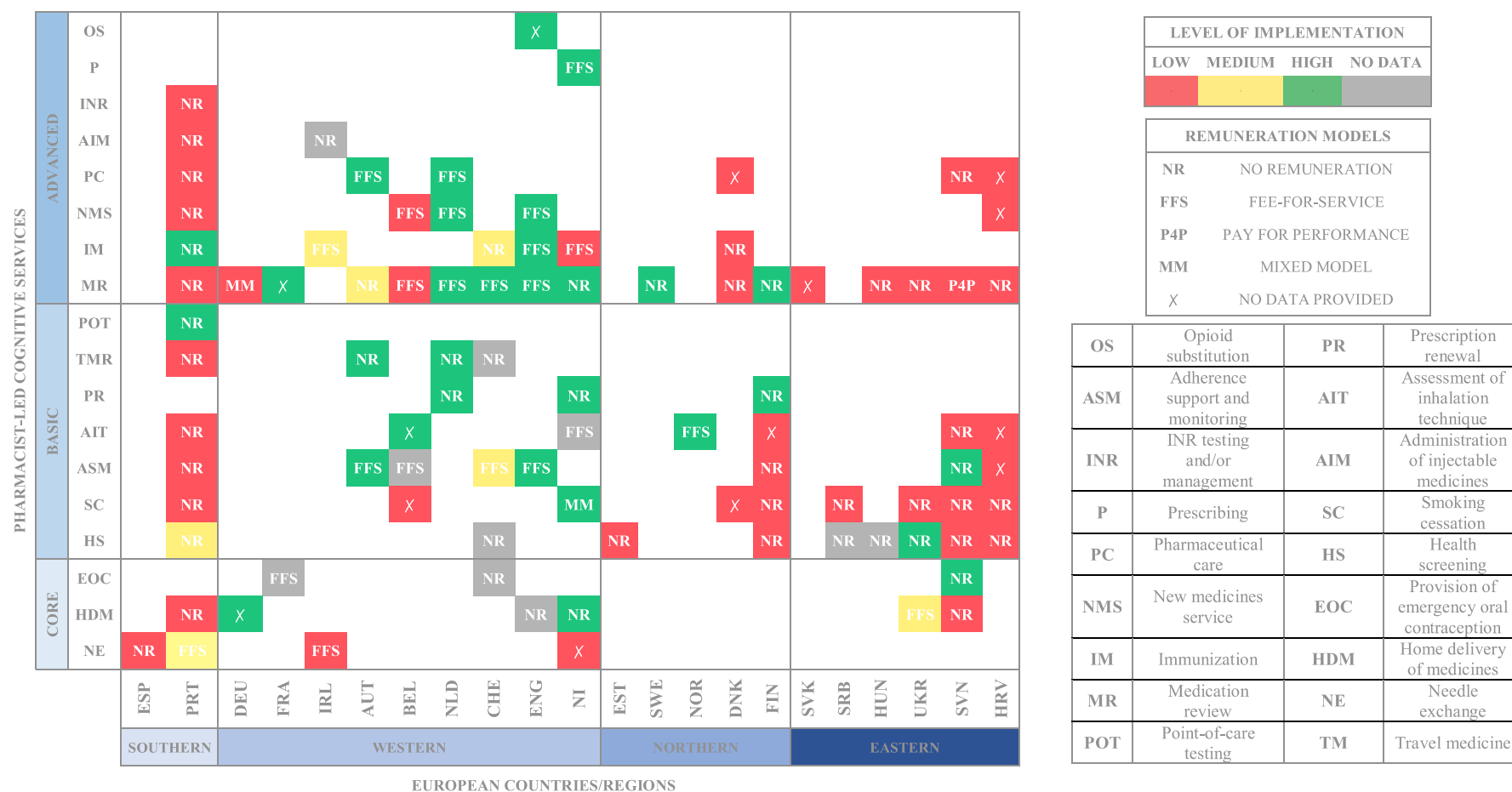


Figure 23 - PLCS Implementation Level/Remuneration Model

4.3.4 – Availability of services by PGEU classification (2010)

For detailed analysis of service availability, the services are categorized into 3 sections according to the PGEU (2010) classification. The tables below provide supplementary information on independent provision or provision as part of medicines dispensing and also indicates the level of implementation and remuneration models for the independently provided services.

Core Services

There are five services that can be included in this category of services: medicines dispensing, provision of medicines' information, generic substitution, provision of EOC, home delivery of medicines and needle exchange. According to the Pharmaceutical Group of the European Union, (2010) these are essential services provided by all licensed pharmacies during core pharmacy opening hours. Table 6 provides additional information on core services.

Data suggests within the five core services provided in European pharmacies the most commonly available is medicine dispensing (100%, n=34), provision of medicines' information (94.1%, n=32), generic substitution (85.3%, n=29) and provision of EOC (70.6%, n=24). The least commonly available is needle exchange (23.5%, n=8).

Focusing on core services, our data also suggests that some countries have a wider scope available, namely Portugal and The Netherlands (100%, n=6), Belgium, Finland, Germany, Iceland, Ireland, Malta, Northern Ireland, Slovenia, Switzerland, Ukraine, England, France and Serbia (83.3%, n=5). The countries/ regions that have least core services available are Albania, Bulgaria, Macedonia, Romania, Estonia, Kosovo, Latvia (50%, n=3), followed by Poland (33.3%, n=2).

The service with least available data sent by responders was provision of emergency oral contraception, only reported by Portugal as having a high implementation level in. Home delivery of medicines was reported to be highly implemented in Germany and Northern Ireland, lowly implemented in Portugal and Slovenia, and medium implemented in Ukraine. Needle exchange was reported to be within the lowest implementation level in Ireland, Northern Ireland and Spain, and in the medium level in Portugal. Provision of EOC was reported to be remunerated using a FFS model in France, Home delivery of medicines is only remunerated (using FFS) in Ukraine. Needle exchange is remunerated in Ireland and Portugal with a FFS payment.

Table 6 - Core PLCS available in primary care across Europe. Availability (Level of implementation-Remuneration Model)

Countries/ Regions	Generic substitution	Provision of medicines' information	Provision of emergency oral contraception	Home delivery of medicines	Needle exchange
Albania ¹	No	Yes	Yes	No	No
Austria ¹	No	Yes	Yes	Yes	No
Belgium	Yes	Yes	Yes	No	Yes
Bulgaria ¹	No	Yes	Yes	No	No
Croatia ¹	Yes	Yes	Yes	No	No
Denmark ¹	Yes	Yes	No	Yes	No
Finland ¹	Yes	Yes	Yes	Yes ⁴ (X - X)	No
Germany ¹	Yes	Yes	Yes ⁴ (X - X)	Yes ⁴ (High - X)	No
Hungary ¹	Yes	Yes	No	Yes	No
Iceland ¹	Yes	Yes	Yes	Yes	No
Ireland ¹	Yes	Yes	Yes ⁴ (X - X)	No	Yes ⁴ (Low - FFS)
Luxembourg ¹	Yes	Yes	Yes	No	No
Macedonia ¹	Yes	Yes	No	No	No
Malta ¹	Yes	Yes	Yes	Yes ⁴ (X - X)	No
Northern Ireland ¹	No	Yes	Yes ⁴ (X - X)	Yes ⁴ (High - No)	Yes ⁴ (Low - X)
Norway ¹	Yes	Yes	No	No	Yes ⁴ (X - X)
Poland ¹	Yes	No	No	No	No
Portugal ¹	Yes	Yes	Yes	Yes ⁴ (Low - No)	Yes ⁴ (Medium - FFS)
Romania ¹	Yes	Yes	No	No	No
Slovakia ¹	Yes	Yes	Yes	No	No
Slovenia ¹	Yes	Yes	Yes ⁴ (High - No)	Yes ⁴ (Low - No)	No
Spain ¹	Yes	Yes	No	No	Yes ⁴ (Low - No)
Switzerland ¹	Yes	Yes	Yes ⁴ (X - No)	Yes	No
The Netherlands ¹	Yes	Yes	Yes	Yes	Yes
Turkey ¹	Yes	Yes	No	Yes ⁴ (X - X)	No
Ukraine	Yes	Yes	Yes	Yes ⁴ (Medium - FFS)	No
England ²	No	Yes	Yes ⁴ (X - X)	Yes ⁴ (X - No)	Yes ⁴ (X - X)
Estonia ²	Yes	Yes	No	No	No
Kosovo ²	Yes	Yes	No	No	No
Latvia ²	Yes	No	Yes	No	No
Sweden ²	Yes	Yes	Yes	No	No
France ³	Yes	Yes	Yes ⁴ (X - FFS)	Yes	No
Georgia ³	Yes	Yes	Yes	No	No
Serbia ³	Yes	Yes	Yes	Yes ⁴ (X - X)	No

¹ Full validation of Data (all participants or majority) ² Partial validation of data (one participant); ³ No validation of data (no participants)

⁴ Provided as an independent service - provided as an "add-on" to medicines dispensing or as a service that is provided totally separate from medicines dispensing. Data on level of implementation and remuneration models only concerns independent provision. |

X - No data provided; No - No Remuneration (0€); P4P - Pay for Performance; FFS - Fee-for-service; MM - Mixed Model

Basic Services

Seven services are included in this category: assessment of inhalation technique, adherence support and monitoring, smoking cessation counselling, health screening, travel medicine, prescription renewal and point-of-care-testing. The definition for this services is provided by the (Pharmaceutical Group of the European Union, 2010) as services that may require separate consultation facilities and special training of pharmacy staff; may need to be available outside core pharmacy opening hours (*e.g.* during the night). Table 7 provides additional information on basic services.

Data suggests that within the seven basic services provided in European pharmacies, the most commonly available are point-of-care testing (67.6%, n=23), assessment of inhalation technique (64.7%, n=22), smoking cessation counselling (55%, n=19), adherence support and monitoring (47.1%, n=16), health screening (44.1, n=15). The least commonly available are: travel medicine (23.5%, n=8) and prescription renewal (20.6%, n=7).

Again, as in the previous section, we could see that some countries/regions have a wider scope of basic services available, namely England (100%, n=7), Austria, Finland, Portugal, Switzerland and The Netherlands (85.7%, n=6). The countries/ regions that have least basic services available are Ireland (14.2%, n=1) followed by Hungary, Romania, Slovakia and Latvia (28.9% n=2). Macedonia, Turkey and Kosovo do not have any basic service available in community pharmacies.

Point-of-care testing was only reported to have a high level of implementation in Portugal. Prescription renewal and adherence support monitoring were the two services more often reported to have highest implementation levels in Finland, Northern Ireland and The Netherlands. Smoking cessation is available with low implementation levels in eight countries namely Belgium, Croatia, Denmark, Finland, Portugal, Slovenia, Ukraine and Serbia.

The basic service more often reported as having compensation across Europe was adherence support and monitoring, remunerated in Austria, Belgium, Switzerland and England based on a fee-for-service model. Smoking cessation is remunerated in Northern Ireland with a mixed model and assessment of inhalation technique is compensated in Northern Ireland and Norway with a fee-for-service model.

There is no remuneration for the provision of health screening in nine countries and smoking cessation technique, in six countries.

Table 7 - Basic PLCS available in primary care across Europe. Availability (Level of implementation - Remuneration model)

Countries/ Regions	Assessment of inhalation technique	Adherence support and monitoring	Smoking cessation	Health screening	Travel medicine	Prescription renewal	Point-of-care testing
Albania ¹	Yes	No	Yes	No	No	No	Yes
Austria ¹	Yes	Yes ⁴ (High - FFS)	Yes	Yes ⁴ (X - X)	Yes ⁴ (High - No)	No	Yes
Belgium	Yes ⁴ (High - X)	Yes ⁴ (X - FFS)	Yes ⁴ (Low - X)	No	No	Yes	Yes
Bulgaria ¹	Yes	No	Yes	No	No	No	Yes
Croatia ¹	Yes ⁴ (Low - X)	Yes ⁴ (Low - X)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	No	No	Yes
Denmark ¹	Yes ⁴ (X - X)	Yes	Yes ⁴ (Low - X)	No	No	No	No
Finland ¹	Yes ⁴ (Low - X)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	No	Yes ⁴ (High - No)	Yes
Germany ¹	Yes ⁴ (X - X)	Yes ⁴ (X - X)	No	No	Yes ⁴ (X - X)	No	Yes ⁴ (X - X)
Hungary ¹	No	Yes	No	Yes ⁴ (X - No)	No	No	No
Iceland ¹	Yes	No	Yes	No	No	No	Yes
Ireland ¹	No	No	No	No	No	No	Yes ⁴ (X - X)
Luxembourg ¹	Yes	No	No	No	Yes	No	Yes
Macedonia ¹	No	No	No	No	No	No	No
Malta ¹	Yes	Yes	No	No	No	No	Yes
Northern Ireland ¹	Yes ⁴ (X - FFS)	No	Yes ⁴ (High - MM)	No	No	Yes ⁴ (High - No)	Yes ⁴ (X - X)
Norway ¹	Yes ⁴ (High - FFS)	Yes	No	Yes ⁴ (X - X)	No	No	No
Poland ¹	No	No	No	No	No	No	No
Portugal ¹	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	Yes ⁴ (Medium - No)	Yes ⁴ (Low - No)	No	Yes ⁴ (High - No)
Romania ¹	Yes	No	Yes	No	No	No	No
Slovakia ¹	No	No	Yes ⁴ (X - X)	No	No	No	Yes
Slovenia ¹	Yes ⁴ (Low - No)	Yes ⁴ (High - No)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	No	Yes	No
Spain ¹	No	No	Yes ⁴ (X - X)	No	No	No	No
Switzerland ¹	Yes	Yes ⁴ (Medium - FFS)	No	Yes ⁴ (X - No)	Yes ⁴ (X - No)	Yes	Yes ⁴ (X - X)
The Netherlands ¹	Yes	Yes	Yes	No	Yes ⁴ (High - No)	Yes ⁴ (High - No)	Yes
Turkey ¹	No	No	No	No	No	No	No
Ukraine	No	No	Yes ⁴ (Low - No)	Yes ⁴ (High - No)	No	No	Yes
England ²	Yes ⁴ (X - X)	Yes ⁴ (High - FFS)	Yes ⁴ (X - X)	Yes ⁴ (X - X)	Yes ⁴ (X - X)	Yes	Yes ⁴ (X - X)
Estonia ²	Yes	No	No	Yes ⁴ (Low - No)	No	No	No
Kosovo ²	No	No	No	No	No	No	No
Latvia ²	No	No	No	Yes	No	No	Yes
Sweden ²	Yes	Yes	No	Yes ⁴ (X - X)	No	No	Yes
France ³	No	Yes	Yes	Yes	Yes	No	Yes ⁴ (X - X)
Georgia ³	No	No	No	No	No	No	Yes
Serbia ¹	Yes	No	Yes ⁴ (Low - No)	Yes ⁴ (X - No)	No	No	Yes

¹ Full validation of Data (all participants or majority) ² Partial validation of data (one participant); ³ No validation of data (no participants)

⁴ Provided as an independent service - provided as an "add-on" to medicines dispensing or as a service that is provided totally separate from medicines dispensing. Data on level of implementation and remuneration models only concerns independent provision.

X - No data provided; **No** - No Remuneration (0€); **P4P** - Pay for Performance; **FFS** - Fee-for-service; **MM** - Mixed Model

Advanced Services

Advanced services are those that require separate consultation facilities in the pharmacy and accredited pharmacists to provide it (Pharmaceutical Group of the European Union, 2010). In this category nine service were included, namely pharmaceutical care, opioid substitution, new medicines service, immunization, administration of injectable medicines, personalised medicine, prescribing, INR testing and/or management and medication review.

Data suggests the most commonly advanced services available in European pharmacies are medication review (79.4% of countries, n=27), opioid substitution (52.9%, n=18), pharmaceutical care (44.1%, n=15), new medicines service (35.3%, n=12), immunization (17.6%, n=6), INR testing and/or monitoring, prescribing, administration of injectable medicines (5.9%, n=2) and personalized medicine (2.9%, n=1). Table 8 provides additional information on advanced services.

Again, data suggests that some countries have a wider scope of basic services available namely Portugal and England (66.6%, n=6), Denmark (55.5%, n=5). The countries/ regions that have least basic services available are Iceland (11.1%, n=1) followed by Hungary, Luxemburg, Norway, Spain, Ukraine and Georgia (22.2% n=2). Macedonia, Poland, Romania, Turkey and Kosovo do not have any advanced service available in community pharmacies.

Medication review was reported to be highly implemented in seven countries, Finland, Northern Ireland, Switzerland, The Netherlands, England, Sweden and France. Opioid substitution was the service reported with high implementation in namely in Luxemburg, Switzerland and England. Pharmaceutical care was the service reported to have low implementation in more countries, Croatia, Denmark, Portugal and Slovenia.

Medication review, regardless of the type, appears to be the service where more countries/regions remunerate the community pharmacy/pharmacist for the provision of the service. It is remunerated in Belgium, Germany, Slovenia, Switzerland, The Netherlands and England. Most of the countries have a fee-for-service model, except for Germany performing a mixed model and Slovenia performing a pay-for-performance model. Opioid substitution is remunerated in Ireland, Luxemburg, Northern Ireland, Norway and Switzerland, in all of them using a fee-for-service model. There is no remuneration for the provision of administration of injectable medicines in none of the countries/regions surveyed.

Table 8 - Advanced PLCS available in primary care across Europe. Availability (Level of implementation - Remuneration model)

Countries/Regions	Pharmaceutical care	Opioid substitution	New medicines service	Immunisation	Administration of injectable medicines	Personalised medicine	Prescribing	INR testing and/or management
Albania ¹	Yes	No	Yes	No	No	No	No	No
Austria ¹	Yes ² (High - FFS)	Yes	Yes	No	No	No	No	No
Belgium ¹	Yes	Yes ² (X - X)	Yes ² (Low - FFS)	No	No	No	No	No
Bulgaria ¹	Yes	No	Yes	No	No	No	No	No
Croatia ¹	Yes ² (Low - X)	Yes	Yes ² (Low - X)	No	No	No	No	No
Denmark ¹	Yes ² (Low - X)	Yes ² (X - X)	Yes	Yes ² (Low - No)	No	No	No	No
Finland ¹	Yes	Yes	No	No	No	No	No	No
Germany ¹	Yes ² (X - X)	Yes ² (X - X)	No	No	No	Yes ² (X - X)	No	No
Hungary ¹	Yes	No	No	No	No	No	No	No
Iceland ¹	No	No	No	No	No	No	No	No
Ireland ¹	No	Yes ²	No	Yes ² (Medium - FFS)	Yes ² (X - No)	No	No	No
Luxembourg ¹	No	Yes ²	No	No	No	No	No	No
Macedonia ¹	No	No	No	No	No	No	No	No
Malta ¹	No	No	No	No	No	No	No	No
Northern Ireland ²	No	Yes ²	No	Yes ² (Low - FFS)	No	No	Yes ² (High - FFS)	No
Norway ¹	No	Yes ²	No	No	No	No	No	No
Poland ¹	No	No	No	No	No	No	No	No
Portugal ¹	Yes ² (Low - No)	No	Yes ² (Low - No)	Yes ² (High - No)	Yes ² (Low - No)	No	No	Yes ² (Low - No)
Romania ¹	No	No	No	No	No	No	No	No
Slovakia ¹	No	No	No	No	No	No	No	No
Slovenia ¹	Yes ² (Low - No)	Yes	No	No	No	No	No	No
Spain ¹	Yes ² (X - X)	Yes ² (X - X)	No	No	No	No	No	No
Switzerland ¹	No	Yes ²	No	Yes ² (Medium - No)	No	No	No	No
The Netherlands ¹	Yes ² (High - FFS)	Yes ² (X - X)	Yes ² (High - FFS)	No	No	No	No	No
Turkey ¹	No	No	No	No	No	No	No	No
Ukraine ¹	Yes	No	No	No	No	No	No	No
England ²	No	Yes ² (High - X)	Yes ² (High - FFS)	Yes ² (High - FFS)	No	No	Yes ² (X - X)	Yes ² (X - X)
Estonia ²	No	No	Yes	No	No	No	No	No
Kosovo ²	No	No	No	No	No	No	No	No
Latvia ²	No	No	No	No	No	No	No	No
Sweden ²	Yes ² (X - X)	Yes ² (X - X)	Yes	No	No	No	No	No
France ¹	No	Yes	Yes ² (X - X)	No	No	No	No	No
Georgia ¹	No	Yes ²	No	No	No	No	No	No
Serbia ¹	No	No	No	No	No	No	No	No

¹ Full validation of data (all participants or majority)² Partial validation of data (one participant); ³ No validation of data (no participants)

² Provided as an independent service - provided as an "add-on" to medicines dispensing or as a service that is provided totally separate from medicines dispensing. Data on level of implementation and remuneration models only concerns independent provision.

X - No data provided; **No** - No Remuneration (0€); **P4P** - Pay for Performance; **FFS**

Medication Review

Medication review has been reported by 27 countries/regions, referring to at least one type of MR (79.4%). However, only 19 of these countries/regions provide the service as separate service either as a project or as an established service (55.9%). The results of MR will be presented considering the MR services only provided as independent services. The Pharmaceutical Care Network Europe, has stated that the most widely disseminated type of MR in 2016 was type 2a MR (41.8%, n=14) followed by type 1 MR (38.2%, n=13), type 3 MR (17.6%, n=6) and type 2b MR (11.7%, n=4) (see Table 9). However, the latest PGEU report assumes that MR type 1 is provided in 100% of the member countries (Pharmaceutical Group of the European Union, 2017b).

Without considering the services provided as part of a project, countries/regions reporting to provide more MR services are: Finland (n=4), England, Northern Ireland and Slovenia (n=3). England and Slovenia are providing type 2a, 2b and type 3 MR while Northern Ireland is providing type 1, type 2a and type 2b MR. The implementation level of at least one type of MR was reported by 19% countries/regions (100%).

From the four types where data were obtained, the majority (73.5%) revealed low levels of implementation, followed by high implementation found in 23.5% and a minority (2.9%) reported medium level of implementation. Observing the remuneration model for this service, at least one type of model was reported by each country/region. In the majority of the countries/regions (54.6%, n=20) there was no remuneration for the provision of MR. However, the remaining 32.4% (n=13) were predominantly based on a FFS model (24.3%, n=9), followed by P4P model (5.4%, n=2) and MM model (2.7%, n=1).

Type 1 MR

Type 1 MR is provided as an independent in 13 countries/regions (38.2%). The majority (69.2%, n=9) were provided as national service and 30.8% were provided as part of projects and studies. High implementation (67-100%) was reported in Finland, France, Switzerland and the Netherlands and low implementation (1-33%) was reported in Croatia, Denmark, Hungary, Norway, Slovakia and Ukraine. A remuneration for the type 1 MR service existed in 15.4% (n=2) of the countries/regions. In Switzerland, community pharmacies are compensated for the provision of the service, with a specific fee for each

prescription and an additional fee for each prescribed product. In Germany there is a remuneration for one ongoing project, which is described as a flat fee.

Type 2a MR

Type 2a MR as an independent service is available in 14 countries/regions across Europe (41.8%). The service is provided as part of a project or study in 28.5% (n=4), including Belgium, Denmark, Germany, and Spain. The type 2a MR were reported to have either high low implementation of the service. Most of the countries/regions reported to provide this service within a low level implementation, such as Belgium, Croatia, Denmark, Finland, Germany, Hungary, Portugal, Slovenia and Ukraine. High implementation was reported in England, Northern Ireland and Sweden and medium implementation (34-66%) was reported in Switzerland. There was a FFS model of remuneration reported in Belgium, Germany, Northern Ireland, Switzerland and England. In Croatia, Finland, Hungary, Northern Ireland, Portugal, Slovenia, Sweden and Ukraine the pharmacist does not receive any form of remuneration for service provision.

Type 2b MR

Type 2b MR is provided as separate national service in 4 countries/regions (11.7%). Three countries/regions (Finland, Slovenia and England) reported to have a low implementation level for the service. Only Northern Ireland did not report any level of implementation. The remuneration of these type MR varies in the different countries, the pharmacist in Finland were not remunerated for the performance of the type 2b MR, whereas in Slovenia pharmacist get a remuneration for the service based on a pay-for-performance model. In England and Northern Ireland there was no information reported about the funding of the type 2b performed in community pharmacies.

Type 3 MR

Type 3 MR service were available in six countries/regions (17.6%). Germany reported to currently have an ongoing project. Only The Netherlands reported to have a high level of implementation. Austria, Finland, Germany, Slovenia and England reported

to perform the service with a low level of implementation. In 66.7% (n=4) of the countries/region the pharmacist received a remuneration for the service, either as FFS, P4P or MM model. In England no information about the remuneration of the type 3 MR services were reported, although there are official publicly available sources that describe the remuneration model.

Table 9 - Availability of MR services by type

Countries/Regions	Medication Review Type 1	Medication Review Type 2a	Medication Review Type 2b	Medication review Type 3
Albania ¹	Yes	No	No	No
Austria ¹	Yes ⁴ (X - X)	Yes	No	Yes ⁴ (Low - FFS)
Belgium ¹	No	Yes ⁴ (Low - FFS) - P	No	No
Bulgaria ¹	Yes	No	No	No
Croatia ¹	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	No	No
Denmark ¹	Yes ⁴ (Low - No) - P	Yes ⁴ (Low - No) - P	No	No
Finland ¹	Yes ⁴ (High - No)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)	Yes ⁴ (Low - No)
Germany ¹	Yes ⁴ (X - FFS) - P	Yes ⁴ (Low - FFS) - P	No	Yes ⁴ (Low - MM) - P
Hungary ¹	Yes ⁴ (Low - No) - P	Yes ⁴ (Low - No) - P	No	No
Iceland ¹	Yes	No	No	No
Ireland ¹	Yes	No	No	No
Luxembourg ¹	Yes	No	No	No
Macedonia ¹	No	No	No	No
Malta ¹	Yes	No	No	No
Northern Ireland ¹	Yes ⁴ (X - No)	Yes ⁴ (High - FFS)	Yes ⁴ (X - X)	No
Norway ¹	Yes ⁴ (Low - No)	No	No	No
Poland ¹	No	No	No	No
Portugal ¹	No	Yes ⁴ (Low - No)	No	No
Romania ¹	No	No	No	No
Slovakia ¹	Yes ⁴ (Low - No) - P	No	No	No
Slovenia ¹	No	Yes ⁴ (Low - No)	Yes ⁴ (Low - P4P)	Yes ⁴ (Low - P4P)
Spain ¹	No	Yes (X - X)	No	No
Switzerland ¹	Yes ⁴ (High - FFS)	Yes ⁴ (Medium - FFS)	No	No
The Netherlands ¹	Yes ⁴ (High - No)	No	No	Yes ⁴ (High - FFS)
Turkey ¹	No	No	No	No
Ukraine ¹	Yes ⁴ (Low - No)	Yes ⁴ (Low - No) - P	No	No
England ²	No	Yes ⁴ (High - FFS)	Yes ⁴ (Low - X)	Yes ⁴ (Low - X)
Estonia ²	No	No	No	No
Kosovo ²	No	No	No	No
Latvia ²	Yes	No	No	No
Sweden ²	No	Yes ⁴ (High - No)	No	No
France ³	Yes ⁴ (High - X)	No	No	No
Georgia ³	Yes	No	No	No
Serbia ³	Yes	No	No	No

¹ Full validation of data (all participants or majority); ² Partial validation of data (one participant); ³ No validation of data (no participants)

⁴ Provided as an independent service - provided as an "add-on" to medicines dispensing or as a service that is provided totally separate from medicines dispensing. Data on level of implementation and remuneration models only concerns independent provision.

X - No data provided; **No** - No Remuneration (0€); **P4P** - Pay for Performance; **FFS**; **P** - Project/Study

4.3.4 – Pharmacist-led Cognitive Services in Portugal

Portugal is providing 18 out of 22 listed PLCS (81.8%). The majority of the services (70%) revealed low levels of implementation, followed by medium implementation found in 15% of the PLCS and a minority of PLCS (10%) reported to be provided with high level of implementation. Within the independent services, needle exchange was the only service that had a co-payment from the NHS on a fee-for-service plan. Additionally, generic substitution, that is only provided as part of medicines dispensing, i.e., not classified as an independent service, is remunerated by the NHS with a fixed fee of 0.35€ per package.

Table 10 describes the specific data on PLCS available in Portuguese pharmacies.

Table 10 - Reported availability, implementation and remuneration of PLCS in Portugal

PLCS	Implementation	Remuneration	Payer
Medicines dispensing	100%	Regressive margins (Ministerial Order nº 195-C/2015)	NHS
Point of care testing	90%	X	OOP/insurer (1.5-5 €)
Immunisation	78%	X	OOP (2.50 €)
Health screening	50%	X	X
Needle exchange	20% (54%*)	FFS (Ministerial Order nº 301-1/2016)	NHS (2.4 €/kit)
Generic substitution	47.5% (48.2%**)	FFS (Ministerial Order n.º 262/2016)	NHS (0,35€/package)
Administration of injectable medicines	30%	X	OOP (2.50 €)
Assessment of inhalation technique	20%	X	X
Adherence support and management	10%	X	OOP (15 €/month)
MR type 2a	10%	X	X
Home delivery of medicines	7.50%	X	OOP (5€/delivery)
Smoking cessation	5%	X	OOP (10 €/month)
Pharmaceutical care	5%	X	OOP (15 €/month)
INR management	5%	X	OOP (10 €/month)
Travel medicine	4%	X	OOP (10 €/service)
New medicines service	1%	X	X
Prescription renewal	0%	X	X
Opioid substitution	0%	X	X
Prescribing	0%	X	X
Personalised medicine	0%	X	X
Provision of medicines' information	NDA	X	X
Provision of EOC	NDA	X	X

X - No Remuneration; OOP - Out-of-Pocket; NHS - National Health Service; NDA - No Data Available; (Data from public sources); *Source: PORDATA 2015; Needle Exchange Programme -DGS, 2015;

**Source: INFARMED, 2018

Chapter 5 – Discussion

This thesis reflects the results of a study that expands and updates the information on PLCS availability across Europe between 2016 and 2017. Therefore, three components of these PLCS were studied: availability, implementation level and remuneration models.

The sample of this study was improved compared to previous work published, including that developed by our team and other work by well-known researchers. In the current study, 34 countries participated in the survey compared to the work by Martins *et al.*, (2015) where 19 countries replied to the survey. In addition, there is an update not only on the number of countries that were approached but also on the number of PLCS included in the questionnaire. In the study by Bulajeva *et al.*, although exclusively focused on MR, it is worth reporting that 25 countries were involved (Bulajeva *et al.*, 2014).

5.1 – Availability, implementation and remuneration of PLCS

Availability

The main findings suggest that almost half the countries/regions (41.1%, n=14) are providing at least 12 of the 22 PLCS listed. Many of these services have evidence of contributing to better patient outcomes, including health-related quality of life (Curran; *et al.*, 2012; Nkansah *et al.*, 2010).

Comparing our study results, which pertain to 2016, with 2015 data from the PGEU an evolution in the number of countries providing PLCS is clearly observed, despite the inherent methodological limitations of such a direct comparison. There are, however, discrepancies in these two sources of information, which may be due to several aspects worth exploring. Looking at the data for the immunization service as an example, we have found seven countries, whereas PGEU reports nine. This discrepancy may be due to the way countries are considered (*e.g.* UK vs England) or to the way service provision is considered relevant or not; for example, to our knowledge, in Iceland, Finland and the Netherlands the service is provided in pharmacies by other healthcare professionals, which implies it would be excluded in our survey given the definitions of a pharmacist-led service (International pharmaceutical Federation - FIP, 2016a). Also, the fact that we may be using different data collection points may be extremely relevant, as for example in the latest PGEU report issued in 2017, this value increased to twelve

countries (Pharmaceutical Group of the European Union, 2017b). It is also important to recognize that PGEU is an organization with the main goal of advocating the role of the pharmacist and of community pharmacies; hence, pilot studies, such as the one currently running in France are included, whereas in our study we have excluded pilots from the concept of “implemented” in the first section of the study (overview on different pharmacist-led cognitive services). For the second section of the study (MR types), pilot studies were included.

Conversely, the data on the smoking cessation availability is consistent with that reported by the PGEU (2015). Comparing our results with previous work (Martins *et al.*, 2015) there is an increased provision of some services namely smoking cessation, point-of-care testing, pharmaceutical care and immunization. Again, it must be stated that such direct comparisons require careful interpretation as the sample of countries/regions used is not exactly the same.

Findings also suggest that beyond a greater number of providers, new services are also emerging, namely personalized medicine. This is an excellent example of services that appear in an effort to respond to accessibility issues, in which patients would need to attend other healthcare facilities, sometimes distant from where they live.

Currently and as expected, there is a higher proportion of less complex services, the so called ‘core services’. However, there are some exceptions, namely the absence of generic substitution in Albania, Austria, Bulgaria, Northern Ireland and England. However, again methodological aspects require careful analysis because in some of these countries, generic substitution is not considered a service and is part of medicines dispensing, whereas in others, dispensing the brand name following the prescription is indeed compulsory.

In contrast, the least available services were often those considered more complex, where implementation implies additional training, investment in refurbishing or even accreditation of pharmacists and/or premises. Examples include prescribing, administration of injectable medicines and personalized medicine. In addition, some of these services are simply not provided because the legislation forbids it. Southeast Europe countries (*e.g.* Albania, Bulgaria, Macedonia, and Romania) are countries where strict regulations often impede pharmacists to further expand their scope of practice, hence being the laggards in the implementation ladder (Rogers, 2002). As a contributing factor to such discrepancies is the fact that in countries such as Romania and Ukraine, it is still

illegal to manage biological products (*e.g.* blood) in the community pharmacy, hindering the implementation of various services. In Belgium and in The Netherlands, for instance, there is also some controversy on the permission or willingness to touch patients, which is implicit in some activities such as point-of-care testing.

Pharmaceutical care delivery is well documented (Farris *et al.*, 2006) with evidence also of its value for patient outcomes, namely in terms of reducing inappropriate prescribing (Meid *et al.*, 2015; Patterson, Bradley, Kerse, Cardwell, & Hughes, 2015). However, less than half the countries are providing this service (n=15; 44.1%), perhaps because it is perceived as a concept comprising various services more than as a service *per se*. If that is the case, we can assume some respondents have considered the new medicines services, medication review, assessment of inhalation technique and adherence monitoring and supporting as part of pharmaceutical care and others as specific services.

This aspect was minimized by using the MeSH terms throughout the survey, while realizing that practitioners may perceive the reality according to their experience, which is a direct consequence of the services implemented in their country. This problem had already been reported in a previous study by members of this project, where self-reported provision of pharmaceutical care had led to controversial findings believed to result from terms used (F. A. Costa *et al.*, 2017). In the present study responders reporting on distinct services like medication review or adherence support abstained from listing also pharmaceutical care because they probably have no service in their country labelled under this term. We used the PCNE definition which does not really describe a distinct service, and this might be the reason of some misunderstanding and underreporting under this term.

Medication review

The results about MR services across Europe is an update of a prior survey conducted in 2011 by Bulajeva *et al.*, (2014). In 19 of the 34 (56%) of the countries/regions participated in at least one type of MR service is provided, whereas the type 2a MR service (14/34; 41%) and Type 1 MR were the most widespread MR services. These can indicate that that the MR using the medication history and a patient interview as source of information are more feasible to perform in the community pharmacy, than type 2b and type 3 where clinical conditions and laboratory test results are needed. These

findings are similar to the results of the prior survey by Bulajeva *et al.*, where Slovenia and England pharmacists reported performing MR type 2b and 3 within a GP practice or healthcare centre, where clinical conditions and laboratory test results of patients are available, whereas in the Netherlands and in Finland, the community pharmacies have only access to the clinical patient information.

Regarding the level of implementation, the number of community pharmacies providing these services varied from <1% to 100%. Type 1 MR service was provided in 38% (13/34) of the participating countries/regions, whereas the PGEU reported that type 1 MR is provided by 100% of the European pharmacies as this is part of the mandatory dispensing process (PGEU Annual Report 2017). Type 2 MR in accordance to PGEU consists of a structured patient consultation focusing on adherence and medicines use to be provided in 53%, whereas in our survey 39% (14/36) of the participants indicated to offer type 2a MR services, either as implemented service or ongoing project. (PGEU Report 2017) This variance in the percentages appeared, because our survey focused on MRs performed as a separate and structured service. In countries with medium or higher implementation as *e.g.* the Netherlands, England, Finland and Switzerland the services were initiated nationally few years ago, which indicated that large-scale implementation is time consuming.

The Netherlands have a high level of implementation of MR services (~100% for type 1 and type 3 MR services), because Dutch pharmacies are obliged to do type 1 MRs and since the last year the inspectorate also monitors the performance of type 3 MRs. A change in behaviour, like the one needed for the implementation of new services, is feasible, but challenges of different levels (personal, team, institution, wider environment) need to be overcome (Grol & Grimshaw, 2003). On the other hand, these results may show that lack of remuneration cannot be the main barrier for the provision of PLCS. For instance, Finland is providing the four types of MR but none of them is remunerated.

In total 12 MR services are remunerated either by the government (national health service) or health insurances. In comparison with other pharmacist-led cognitive services, MR service was reported to be the most frequent remunerated service, albeit less than one-third of all the reported services were remunerated (32.4%, 12/37) by the government or the health insurances. Only 14.3 (2/14) of the provided type 1 MR services were remunerated compared to type 3 MR services with 66.7% (4/6), suggesting higher

complexity may be linked to higher odds of payment, perhaps also to higher odds of achieving positive patient outcomes. However, it is worth also acknowledging that the human and financial resources needed to perform a type 3 MR review are far higher than for type 1 MR.

Implementation Level and Remuneration Models

Universal health coverage implies services should be readily accessible to all the population (100%). However, our data shows only 17.9% of PLCS are being provided in 100% of pharmacies within each country/region

The wide variation of implementation levels reported for PLCS, aide with the high number not even reporting these data, suggests data available within countries to monitor service provision is probably scarce or outdated.

Although the level of service provision has been increasing, the lack of remuneration or incentives are recognized barriers for the provision of PLCS (Roberts *et al.*, 2006). Some countries have mentioned remunerated PLCS, either based on a FFS, P4P and mixed model between these two. The most commonly found remuneration model was the traditional fee-for-service payment model. Medication review in Slovenia is an exception, where a P4P model is used. However, experts recommend a transition into a population-based payment, as it is a model based on providing the strongest incentives to deliver high quality and efficient care (Alternative Payment Model Framework & Progress Tracking (APM FPT) Work Group, 2016). More recently, new models have suggested combining elements from FFS and an additional payment in case of a positive outcome (M. M. Rosenthal *et al.*, 2017). Smoking cessation in Northern Ireland and medication review in Germany are illustrations of these mixed economic models.

However, in the majority of cases, remuneration of PLCS is still rare. United Kingdom (UK) and Switzerland are two countries that have been evolving towards implementing specific pharmaceutical care programs, where medication review is an integral part (Hersberger & Messerli, 2016; PSNC, 2015). The successful implementation of Medicines Use Reviews in the UK and Polymedication check in Switzerland, despite the divergent functioning of these two healthcare systems, respectively Beveridge and Bismarck, suggests different remuneration solutions may be found for sustainable PLCS. In most of the remaining countries, this service in its varied formats, is not remunerated

and either provided for free (*i.e.*, the pharmacy takes on the costs) or paid out of pocket (*i.e.*, patients support the cost). In both cases, it is possible that such services become unsustainable (Kaae *et al.*, 2010).

The variation in remuneration values in Beveridge models are generally legislated and may be found in published documents. Hence in countries with those functioning models, variation may only result from lack of interest in finding the correct value or using outdated sources. In Bismarck models, variation is easier to understand as payments may vary by insurance companies, hence difficult to find. Despite recognizing the importance of knowing the implementation levels for adequate assessment of service provision, our study shows the difficulties of providing such values given the high proportion of missing data, perhaps because the countries do not know it themselves or because this data is perceived as highly sensitive (Hossain *et al.*, 2017; Moullin, Sabater-Hernández, García-Corpas, Kenny, & Benrimoj, 2016).

Public resources invested in health care are progressively seen as investments to be wisely managed and as needing to ensure maximum gains for the patient and the health care system, with minimum losses. It is crucial that the value of PLCS within primary care is recognized and community pharmacists are seen as allies to cost-effective attainment of patient outcomes (OECD/European Observatory on Health Systems and Policies, 2017).

5.2 – Legal framework and implications in Portugal

In 2007, Decree-Law 307/2007 and Ministerial Order 1429/2007 brought new directives for the community pharmacy and the pharmacist to follow, including the ability for the pharmacies to provide pharmaceutical services beyond medicines dispensing.

Our study revealed that Portugal is providing 18 out of 22 listed PLCS (81.8%) , five of them are described in this decree-law and one defined in the Ministerial Order n.º 97/2018 defined by the ministry of health. The service ‘health screening’, foreseen by law since 2007, is implemented and being performed in 50% of the community pharmacies. In these screening events, various programmes may be included, namely in the dermocosmetic area, hearing, memory, designed for specific non-communicable diseases such as osteoporosis, colorectal cancer, or for some specific areas such as cardiovascular and diabetes.

The needle exchange programme has been initiated in 1993, resulting from a collaboration between the National Association of Pharmacies and the National Committee Fighting Against Aids – CNLCS, through which financing for the programme was always ensured. Between 1993 and 2008 a total of 43045293 needles have been collected, 30317392 of which in community pharmacies. The number of pharmacies involved ranged between 1212 (2000) and 1685 (1994). In fact, according the National Coordinator of the CNLCS in 2008, Prof. Henrique de Barros, when announcing that the proportion of HIV infections associated to the use of injectable drugs decreased from 50% in the nineties to below 20%, clearly stated that “The role of the Pharmacies was determinant for responding to the infection by HIV/AIDS problem among injectable drug users. It was a model worth replicating!”

However, this activity was purely made for the good of humanity and of public health and as such, since 2002, the National Association of Pharmacies decided to initiate the development of research studies to value the contribution of pharmacies for public health. In 2002, Exigo conducted a study that concluded that more than 7,000 new infections have been avoided per 10,000 injectable drug users in the first 7 years of the programme (Exigo, 2002). Later in 2006, another study conducted by CEMBE estimated that the benefit for each exchanged needle was **3,01€** and a reduction in inequalities of 63% (CEMBE, 2016). This evidence led then to the publication of the Ministerial Order 301-A/2016.

During these negotiations, the programme was briefly interrupted, during the entire 2014 for financial and political reasons and then reinitiated during the year 2015.

In 2015 half of the community pharmacies in Portugal were providing this service (Direcção-Geral de Saúde; Serviço Nacional de Saúde, 2015). However, this was prior to the remuneration and also it may be argued that the disruption caused by the temporary cessation of the programme led to changing habits both from the users of injectable drugs and also from the pharmacy teams, which may have compromised the service uptake. The most recent data points to the remuneration of the programme is remunerated since 2016 with a fee of 2.4€ per each kit exchanged (Ministerial Order n. ° 301-A/2016), however there is no recent data on the implementation level.

Point-of-care testing and immunization are two services that fall within the highest level of implementation, with rates of 90% and 80%, respectively, both of which are not remunerated. The payments for these services are made by the patient (out-of-pocket

payment) or by a few insurance companies. The social and economic value that they bring to the patient and the health system has already been described, not only in Portugal but also internationally. The immunization by the pharmacists in the community pharmacy is evolving and increasing and the Portuguese Pharmaceutical Society (PPS) is providing the accreditation of education and training demanded to provide the service (Ordem dos Farmacêuticos, 2013). The future path may enclose the possibility of including more vaccines in the scope of vaccines possible to administer in the community pharmacy, including those within the National Health Plan. However, that would imply full data integration and also shifting the financial resources for disease prevention within primary care. On the other hand, this measure would allow for example, people from rural areas to save time and resources for the immunization.

Traditionally, pharmacists have always been compensated by the profit margin based on product mark-up. However, since 2011 a radical change was made in this system, though which regressive margins were first introduced. These imply that the costlier the medication is, the lower is the profit margin generated for the pharmacy. The initial Ministerial Order has been subsequently updated various times, the most recent in 2015 (Ministerial Order 195 C/2015; Ministerial Order 154/2016), which foresees an additional variable fee component, which varies proportionally to the medication price and can range between 0.63€ and 8.28€. This fee may be seen as a form of payment for the act of dispensing the medicine, which encompasses much more than a simple transaction and should be complemented with the provision of information to ensure the rational use of medicines.

The following year, in 2016, in addition to this general rule, applicable to all prescription medicines, there is also a specific incentive for generic substitution became recognised (Ministerial Order 262/2016). This incentive, although also minimal, 0,35€ per package may also be seen as a form of recognising the pharmacist for his service.

So, the climate seems to be propitious in legislative changes and one could eventually anticipate further expansion of paid services. However, the history also suggests that not always the demonstration of gains is coincident with policy options.

In 2003, an agreement was signed by National Association of Pharmacies (NAP), the Ministry of Health (MH), and the PPS for the reimbursement of level II diabetes disease management programme (including adherence support and management), paid based on a FFS service model. The programme was further evaluated and in 2008 the

remuneration was set at 15€ per patient per month - 75% co-funded by the ministry of health and 25% by the patient. In 2010, this agreement came to an end and since then no further research or developments about this programme were undertaken (S. Costa, Santos, & Silveira, 2006).

In 2014, the NAP and the MH have agreed on a strategy towards the programmes provided by pharmacists to promote public health such as self-management of diabetes, monitoring of adherence, administration of seasonal flu vaccines, needle exchange, administration of opioid substitution therapy, and increase in the generic market (Ordem dos Farmacêuticos; ANF; AFP; MS, 2013)

At this time, Portugal had two PLCS reimbursed by the government.

With the integration of these new services such as HCV, HVB and HIV tests, the government should also consider some remuneration, otherwise the patients may not be able to cover the costs and the service will become unsustainable for the pharmacy. Being a new service, it may be assumed that the pharmacy invested in the education and training of the pharmacists (although not compulsory at the moment), and surely in the products to perform the tests (Ministerial Order 97/2018). Another innovative service is also being tested in Lisbon, although the real innovation is in accessibility to medication. With the publication of the Ministerial Order 166/2016, it has been recognised that pharmacies were active agents of care provision and the government should invest in use services available to test measures to support the rational use of medicine. In this context and acknowledging the need for integration with other units within the National Health Care Service, it was decided that an essay would be run to delegate partially the ability to administer specific therapeutic groups, until then restricted to hospital, such as oral oncology therapy and transmittable diseases. The first chosen for testing was the distribution of HIV therapy, which is being run and for which no publicly available data exists yet.

Services in community pharmacies already proven to add social and economic value in the healthcare and this study provides a detailed overview of the services that are in effect being provided in Portugal (Félix et al., 2017). The goal should be to improve the implementation of the existing services since 12 out of 18 services are being provided but with low implementation levels. It has already been discussed that more difficult than implementation is dissemination and ensuring sustainability. Therefore, representative

organisations should focus on improving the steps and stages to implement services and develop the means and incentives to ensure financial viability.

The vision for the future in Portugal is positive, at least on the availability for the pharmacies to provide PLCS. However, strategies to raise the implementation levels and to agree on reimbursement models should be a priority to the Government. It is necessary to think and develop long-term plans that can be pursued by the governments that follow those that implemented the change in their 4-year mandate subsequent. PLCS mainly fall into the disease prevention area, an area where surely longer-term actions need planning and sustainability so that fruitful outcomes may be later obtained at the population level.

5.3 – Study Limitations

Despite the study value, some limitations need acknowledgement. The survey used was based on a large list of pharmacist-led cognitive services resulting from literature review, but it is possible that there might be additional relevant services overlooked. Moreover, although the survey was based on standardized definitions, we must acknowledge, particularly for pharmaceutical care, different interpretations of the service may have occurred. Although we aimed for data triangulation with involvement of three participants from different backgrounds, we have not fully succeeded as in some countries we found it extremely difficult to find a large enough pool of respondents to allow drop-outs. Nonetheless, we believe our approach increased data validity.

This is the first European survey that in addition to gathering information on pharmaceutical services available, also gives a description of characteristics such as implementation and associated remuneration. However, missing data compromises the in-depth knowledge of the provision of PLCS in Europe aimed for. We must be aware that much of these data is not publicly available and that may pose a barrier for experts to share and publish the information. Another limitation was the inability to complement our information with publicly available data to build a more comprehensive roadmap of paid PLS across Europe. Some data are surely difficult to find but those accessible and available in widely used languages could have been useful. However, this was a conscious methodological option taken by the research team as it was considered that different sources of data could generate mismatched results.

5.4 – Potential implication for practice and future research

The results presented in this thesis give insights into the provision of the pharmacist-led cognitive services across Europe, enabling a better overview of these services. Additionally, is the first study reporting the implementation level and the remuneration models of the PLCS.

This study is important for pharmacists that perform their roles in the different areas, not only in community pharmacies and research, but also for policy makers that may have a significant and direct impact on the stakeholders and on the development of new policies and directives. Furthermore, it should be interesting to integrate the community pharmacists performing some of the described PLCS within their daily teams into the broader scope of primary care. Moreover, this study aggregates information about several countries in the EU which can further lead to actions from the European agencies towards the community pharmacy practice.

Prospectively, we believe this project can be used as foundation for future research in which knowledge on health care payment systems is increased since the lack of remuneration is many times pointed out as a barrier for the provision or development of new PLCS but also to the sustainability of the already existing services. It would be interesting to deepen the research about the implementation level of the PLCS. The potential relationship between these two components of the PLCS (implementation and remuneration) should be interesting to study, if there is a direct influence on the availability when the service is remunerated. In the future, it could additionally be interesting to study the patients' perspectives on the availability and provision of the services, the patients' unfulfilled needs but also their awareness and adherence to service provided. Also, the application of the general implementation framework to some specific services could lead to new insights in this subject. With this development, it would be easier to develop guidelines for the provision of some specific and advanced services such as medication review or INR testing and/or management. Identically, new models for pharmacists' education and training could be tested and implemented. This study can work as a foundation to answer the following question: How can the development of these services in community pharmacies redirect some of the workload of GP's or other healthcare professionals, such as nurses, into the pharmacies?

Chapter 6 – Conclusion

This is the first European survey that, not only gathers information on pharmaceutical services available, but also gives a description of characteristics such as implementation and associated remuneration.

Overall, the provision of cognitive pharmaceutical services is widely disseminated across Europe. The availability of PLCS is increasing across Europe when comparing our data with previous studies or the literature. There are countries that stand out, either for the number of services or because the services are already structured and prepared to assist as an example to other countries. There is much variation in the implementation level of services across Europe with reported room for improvement to achieve universal PLCS coverage. There are countries standing out as the early adopters which can lead the path and serve as examples for other countries. With this in mind, it is necessary to point out to both social and economic value of such services to make them fully functional and sustainable on the long term.

Our findings also indicate that data on implementation is either not available or difficult to assess, suggesting databases need to be improved to better plan service provision. Remuneration of PLCS is also spreading but no clear pattern was found that relates service provision with payment. Our findings demonstrate Europe is on the right track but there is a long way to achieve universal PLCS coverage with the corresponding fair remuneration.

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Appendixes

Appendix I – Ethics Commission Approval

Comissão de Ética



Proc. Interno nº 515

Ex.ma Senhora

Maria Inês B. Gonçalves Soares

Monte de Caparica, 26 de outubro de 2016.

Ex.ma Senhora,

Venho comunicar-lhe que o Pedido de Parecer que submeteu à apreciação da Comissão de Ética da Egas Moniz, com o tema denominado **“Practise – PhaRmAcist-led CogniTive Services in Europe – a survey on Remuneration of Pharmacist-led Cognitive with a Focus on Medication Review”**, foi aprovado por unanimidade.

Com os melhores cumprimentos,

A Presidente da Comissão de Ética da Egas Moniz

Prof.ª. Doutora Maria Fernanda de Mesquita

Appendix II – Study Survey

Demographic Data

Please fill in the following demographic data for further questions or check your demographic data and correct all discrepancies.

First name; Surname; Country; Mail

Professional activity

Please, complete the share of time you work for a certain type of professional activity?

Community pharmacy; Student/PhD student; Clinic/Hospital; University/Academic; Association ; Government/Public Health; Other (please specify in the comment box below)

Start Part A - Remuneration of pharmacist-led cognitive services

The following questions concerning the topic "remuneration of pharmacist-led cognitive services". You will be provided with a list of pharmacist-led cognitive services, identified during literature search.

A pharmacist-led cognitive service is defined as a service provided or supervised by the pharmacist, based on a standardized and structured procedure, for the purpose of promoting optimal health and drug therapy and that is not necessarily drug-product related.

For each of them, we would like you to state if they are available in your country. If they are not available or if they are a fix part of the medicine dispensing service (consequently of this remunerated fee), the next service is presented to you. Detailed questions about the remuneration of the medicine dispensing service itself will follow at the end of part A.

Take into account that we are interested in implemented services and projects run as a campaign in 2016, but NOT in pilot studies/projects. Feel free to add additional information about the services in the comment boxes. To make sure, that all participants have the same understanding of a services, a definition for each service will be presented in all questions. Please answer the questions, referring to these definitions. The answering of this part is quicker, if you have a list of pharmacist-led cognitive services and the corresponding fees of your country available next to you. We are aware that fees for national service are confidential data, they will only be collected to calculate statistical figures (range, mean or median), but they will not be reported as country specific information!

14 (Service) Do you have the service 'immunisation' performed or supervised by a pharmacist in community pharmacies in your country?*

• (Definition)

- ☐ Yes, this is a separate service
- ☐ Yes, as part of the medicine dispensing and this fee
- ☐ No

Comment

What is the approximate proportion of pharmacies providing this service? (in %)

How much remuneration does the pharmacy receive for this service in Euro (€)? (please specify the unit measure e.g. per patient, per medicine, per month...) If the service is NOT remunerated, note 0.

Appendix III –List of the 22 pharmacist-led cognitive services and the definitions

Pharmacist-led cognitive service - Service provided or supervised by the pharmacist, based on a standardized and structured procedure, for the purpose of promoting optimal health and drug therapy and is not necessarily drug-product related.

Adapted from: Roberts, A. S., Benrimoj, S. I. C., Chen, T. F., & Williams, K. A. (2006). Implementing cognitive services in community pharmacy: a review of facilitators used in practice change. *The International Journal of Pharmacy Practice*, 163–170. <http://doi.org/10.1211/ijpp.14.3.0002>

Implementation - An effort specifically designed to get best practise findings and related products into routine and sustained use through appropriate change/uptake/adoption interventions.

Adapted from: Curran GM et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50(3):217-26. doi: 10.1097/MLR.0b013e3182408812 [published Online First: 2012/02/09]

Remuneration - Remuneration of services is considered when a payment is made by the government (National Health Service) or the insurer to the pharmacy (or pharmacist) for the provided service.

Adapted from: Houle, S. K. D., Grindrod, K. A., Chatterley, T., & Tsuyuki, R. T. (2014). Paying pharmacists for patient care: A systematic review of remunerated pharmacy clinical care services. *Can Pharm J (Ott)*, 147(4), 209–232. <http://doi.org/10.1177/1715163514536678>

Medicines dispensing - The preparation, packaging, labelling record keeping, and transfer of a drug to a patient or an intermediary, who is responsible for administration of the drug.

Adapted from: Medical dictionary. (n.d.). Drug dispensing | definition of drug dispensing by Medical dictionary. Retrieved April 9, 2018, from <http://medical-dictionary.thefreedictionary.com/drug+dispensing>

Generic substitution - Practise of substituting a pharmaceutical (trade name or generic name) by a pharmaceutical containing the same active ingredients.

Adapted from: The Pharmaceutical Pricing and Reimbursement Information (PPRI) network, & (WHO), W. H. O. (2013). *Glossary of Pharmaceutical Terms*.

Verbal/ written provision of medicines' information - The pharmacist provides written/verbal information on medicines that enhance the quality of patient care, improve patient outcomes, and ensure the prudent use of resources.

Adapted from: Ghaibi, S., Ipema, H., & Gabay, M. (2015). *ASHP Guidelines on the Pharmacist's Role in Providing Drug Information*. *American Journal of Health-System Pharmacy* (Vol. 72). Retrieved from <http://www.ajhp.org/cgi/doi/10.2146/sp150002>

Provision of emergency oral contraception - To officially advise someone to use a treatment (a medicine, therapy, etc.) under specific protocol and/or for specific list of medicines.

Adapted from: WHO. (2018). WHO | Emergency contraception.

Home delivery of medicines - Service consists of having medicines (including prescriptions) delivered to patients' home by pharmacy staff.

Adapted from: HAP Michigan. (n.d.). Prescription Home Delivery | Health Insurance | HAP Michigan. Retrieved April 9, 2018, from <https://www.hap.org/prescription-drug/home-delivery>

Needle exchange - Organized services for exchange of sterile needles and syringes used for injections as a potential means of reducing the transmission of infectious diseases.

Adapted from: MeSH. (1994). Needle exchange program.

Assessment of inhalation technique - Healthcare professionals ensure people with asthma or COPD receive specific training and assessment in inhaler technique.

Adapted from: NICE - National Institute for Health and Care. (n.d.). Asthma | Guidance and guidelines | NICE. Retrieved April 9, 2018, from <https://www.nice.org.uk/guidance/qs25>

Adherence support and monitoring - The Service may include the establishment of an enabling strategy (e.g. reminder system or simplification of the complexity of treatment), whenever appropriate. Service where the pharmacist checks the extent to which a person's behaviour – taking medication (including timing, dosage and frequency) – corresponds with agreed recommendations from a health care provider. This may be achieved using different methods (e.g. questionnaires, prescription refill pill count, etc).

Adapted from: Fenerty, S. D., West, C., Davis, S. A., Kaplan, S. G., & Feldman, S. R. (2012). The effect of reminder systems on patients' adherence to treatment. *Patient Preference and Adherence*, 6, 127–135. <http://doi.org/10.2147/PPA.S26314>

Smoking cessation - Individual behavioural counselling involving scheduled face-to-face meetings. Typically, it involves multiple session and it can be combined with pharmacotherapy. Brief interventions for smoking cessation typically delivered in less than 10 minutes are excluded.

Adapted from: NICE - National Institute for Health and Care. (2013). Nice Guidance.

Health screening - Health screening is the process of identifying healthy people who may be at increased risk of disease or condition.

Adapted from: NHS. (n.d.). NHS population screening explained. Retrieved April 9, 2018, from <https://www.gov.uk/guidance/nhs-population-screening-explained>

Travel medicine - Patient- and trip-related information are gathered to assess the traveller's health risks. People are counselled about food- and water-borne diseases, insect-borne diseases, sexual transmitted diseases, and diseases related to animal bites in the travel destination(s). Additionally, information about vaccines that may be needed to protect travellers against different diseases is provided. Moreover, specific information about the treatment of their chronic diseases during the trip are provided.

Adapted from: Jackson, A. B., Humphries, T. L., Nelson, K. M., & Helling, D. K. (2004). Clinical Pharmacy Travel Medicine Services : A New Frontier, 38. <http://doi.org/10.1345/aph.1E193>

Prescription renewal - Service where the pharmacy/pharmacist assists in the renewal of a prescription for chronic medication. This can be done manually (phone calls, fax) or automated.

Adapted from: Company, E. S. H. (n.d.). Ordering online. Retrieved April 9, 2018, from https://www.express-scripts.com/medco/consumer/helpcenter/help_article.jsp?faq=HelpCenter_Refill-Prescription#A

Point of care testing - Patient diagnoses or patients monitoring of disease condition in the ambulatory setting or at bedside. The results of care are timely and allow rapid treatment to the patient and treatment monitoring.

Adapted from: MeSH. (2015). Point-of-care Testing.

Pharmaceutical care - Pharmaceutical Care is the pharmacist's contribution to the care of individuals in order to optimize medicines use and improve health outcomes. The term medication therapy management can be viewed as synonym.

Adapted from: Hersberger, K. E., Griesse-Mammen, N., Cordina, M., Tully, M. P., Foulon, V., Rossing, C., & Mil, F. J. W. van. (2013). Position Paper on the definition of Pharmaceutical Care 2013. *Pharmaceutical Care Network Europe*.

Opioid substitution - A comprehensive treatment program that involves individualised supply for illicit drug users with a replacement drug, a prescribed medicine (e.g. methadone, buprenorphine), which is usually administered orally in a supervised clinical setting.

Adapted from: Kermode, M., Crofts, N., Kumar, M. S., & Dorabjee, J. (2011). Opioid substitution therapy in resource-poor settings. *Bulletin of the World Health Organization*, 89(4), 243–243. <http://doi.org/10.2471/BLT.11.08685>

New medicines service - This Service will provide support to people who are newly prescribed a medicine to manage a long-term condition, which generally help them to appropriately improve their medication adherence.

Adapted from: PSNC, NHS Employers, Blueprint, T., Commission, R., Care, H., Report, R., ... Gesundheit Österreich GmbH - GÖG. (2013). *Service specification – New Medicine Service (NMS)*. *European Journal of Hospital Pharmacy* (Vol. 21). Retrieved from <http://ejhp.bmj.com/lookup/doi/10.1136/ejpharm-2014-000527>

Immunization - The process of inducing immunity to an infectious agent by administering a vaccine by any of the following routes: intravenous (IV); intramuscular (IM); subcutaneous (SC); Oral.

Adapted from: Pharmacy Guild of Australia. (2014). *Guidelines for Conducting Pharmacist Initiated and Administered Vaccination Service within a New South Wales Community* <http://dx.doi.org/10.1016/j.sapharm.2016.01.005>

Administration of injectable medicines - The act of administering injectable medication by any of the following routes: intravenous (IV); intramuscular (IM); subcutaneous (SC).

Adapted from: Pharmacy Guild of Australia. (2014). *Guidelines for Conducting Pharmacist Initiated and Administered Vaccination Service within a New South Wales Community Pharmacy Environment*. Elsevier Ltd. Retrieved from <http://dx.doi.org/10.1016/j.sapharm.2016.01.005>

Personalised medicine - Clinical, therapeutic and diagnostic approaches to optima disease management based on individual variations in a patient's genetic profile. The main aim of this service is to determine the rate of metabolism of medicines so that the therapy may be adapted accordingly.

Adapted from: Velez, G., Roybal, C. N., Colgan, D., Tsang, S. H., Bassuk, A. G., & Mahajan, V. B. (2016). Precision Medicine. *JAMA Ophthalmology*, 1–7. <http://doi.org/10.1001/jamaophthalmol.2015.5934>

Prescribing - To officially advise someone to use a treatment (a medicine, therapy, etc.) under specific protocol and/or for specific list of medicines.

Adapted from: Merriam-Webster. (n.d.). Prescription Drug | Definition of Prescription Drug by Merriam-Webster. Retrieved April 9, 2018, from [https://www.merriam-webster.com/dictionary/prescription drug](https://www.merriam-webster.com/dictionary/prescription%20drug)

INR testing and/or monitoring - Service that uses the international normalized ratio (INR) to monitor blood coagulation (INR testing). Based on the results pharmacists may advise patients on the need to adapt the dose of oral anticoagulants. (INR management).

Adapted from: Mayo Clinic. (n.d.). Prothrombin time test - About - Mayo Clinic. Retrieved April 9, 2018, from <https://www.mayoclinic.org/tests-procedures/prothrombin-time/about/pac-20384661>

Medication review

Medication Review is a structured evaluation of a patient's medicines with the aim of optimising medicines use and improving health outcomes. This entails detecting drug related problems and recommending interventions.

Adapted from: Pharmaceutical Care Network Europe. (2016). *Position Paper on the PCNE definition of Medication Review 2016*.

Appendix IV– Abstract presented at the 2^o International Congress CiiEM “Translational Research and Innovation in Human in health Sciences” 11–13 June 2017, Monte de Caparica published in *Annals of medicine*

PRACTISE – PhaRMacist-led CogniTlve Services in Europe: preliminary results

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Introduction: The scope of community pharmacy practice varies widely across different countries and health care systems. Cognitive pharmaceutical services are daily provided to the patients in community pharmacies [1]. According to the PGEU, pharmacy services can be divided into: “Core services” (essential services provided by all pharmacies), “Basic services” (may require separate facilities and pharmacy staff training) and “Advanced services” (require accredited pharmacist) [2]. Published literature focuses on pharmacist-led cognitive services available in Europe, but fails to report the implementation level in detail. The main aims of this project are to develop a map of existing pharmacist-led cognitive services in Europe.

Materials and methods: A cross-sectional study was conducted where data were collected using an online survey, sent to a sample of 49 countries. The survey comprised three questions for each of the 22 services listed: provision; implementation level and remuneration. The survey was sent to three representatives per country (community pharmacist, researcher and policy maker), to ensure data triangulation, which also considered official documents publicly available. Consensus was sought using the Delphi adapted method. Preliminary results presented here focus on the implementation level, where the PGEU classification of services was used. Data were expressed by numbers of countries where the service is available and proportion of pharmacies providing it [2]. Ethics approval was obtained from “Comissão de Ética Egas Moniz” (Proc. 515).

Results: Data were obtained from 75 participants in 35 European countries (response rate = 71%). “Core services” ($n = 9$): 57% of the countries provide at least six of these services, including “medicines dispensing” ($n = 35$; 100%), “provision of information on medicines” ($n = 34$; 97%), “generic substitution” ($n = 29$; 85%), “provision of emergency oral contraception” ($n = 27$; 77%), “home delivery of medicines” ($n = 21$; 60%) and “health screening” ($n = 17$; 49%). “Basic services” ($n = 4$): 66% of the countries provide at least 3 of these services including, “assessment of the inhalation technique” ($n = 28$; 80%), “pharmaceutical care” ($n = 23$; 66%), “adherence support and monitoring” ($n = 22$; 63%). “Advanced services” ($n = 9$): Only 12% of the countries provide at least 6 of these services, including “medication review” ($n = 25$; 71%), “opioid substitution management”, “new medicines services” ($n = 18$; 51%), “prescription renewal” ($n = 17$; 37%), “immunization” ($n = 7$; 20%) and “prescribing” ($n = 6$; 17%). The implementation level varied widely for all 3 categories; for example, “health screening” was reported as implemented in 5–100% of pharmacies; “assessment of the inhalation technique” was

reported as implemented in 5–100% of pharmacies and “opioid substitution management” was reported as implemented in 10–100%.

Discussion and conclusions: Preliminary data indicate that “advanced services” are provided in lower proportion than “core and basic services”. The variability found in the implementation level supports the idea that this data is essential to describe reality in accurate terms. This is an ongoing project that aims to fill the current gap in the literature.

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References

- [1] Martins SF, van Mil JWF, da Costa FA. The organizational framework of community pharmacies in Europe. *Int J Clin Pharm*. 2015;37:896–905.
- [2] PGEU, Pharmaceutical Group of the European Union (2010). Providing Quality Pharmacy Services to Communities in Times of Change.

Appendix V– Abstract presented at the 6th working symposium of the Pharmaceutical Care Network Europe (PCNE), 1–3 February 2017, Bled published in *International Journal of Clinical Pharmacy*

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Int J Clin Pharm (2017) 39:601–626

Background Poor adherence to direct oral anticoagulation (DOAC) treatment in practice has been reported. Identifying non-adherent patients is needed to initiate adherence counselling. Because of non-forgiving characteristics, DOACs require strict intake intervals that translate into very high adherence rates. The Polymedication Check (PMC) is a reimbursed intermediate medication review in Switzerland that focuses on adherence and medicines use in outpatients.

Purpose We aimed at assessing whether the affirmative answer to the PMC question “Do you sometimes forget to take your medication?” coincides with a Medication possession ratio (MPR) <90% (non-adherence) in DOAC treated patients.

Method Fifth-year pharmacy students recorded one PMC with an anticoagulated patient during internship in community pharmacies between November 2014 and March 2015. Patient’s refills of the past 12 months were used to calculate a MPR for DOAC if at least two refills were available. Assumptions for the calculation of the MPR were made according to Arnet 2016.

Findings The 69 PMCs concerned DOACs for 30 (43.5%) patients (52% women, 73.0 ± 12.2 years old, 9.9 ± 4.9 medications). The most often prescribed DOAC was rivaroxaban (93.3%), apixaban and dabigatran were marginally prescribed (3.3% each). Five PMC were excluded (poor documentation, $n = 2$; less than two refills, $n = 3$). Refills (mean of 2.9 ± 0.8 per patient) were available for a mean of 128 ± 62 days. MPR ranged from 50.6 to 182.7%. MPR below 90% was observed in 4 patients (16%), out of them two self-reported to sometimes forget to take the DOAC. Other two patients reported non-adherence but showed a MPR > 90%.

Conclusion This pilot study shows that deviant behavior is confirmed by calculation of medication possession ratio for only half of the adherers of non-adherence, probably due to the masking of a recent behavior into an averaging calculation method. We question the appropriateness of calculation methods from refills (such as the MPR) as single trigger to adherence counselling. MPR does insufficiently mirror recent non-adherence or disclosed forgetfulness.

community pharmacy practise are desired. Therefore, mainly members of PCNE and ESCP are invited. A key representative is approached for each country known to the project team who is invited to suggest two further participants from their country to fulfil the perspectives from all three backgrounds.

Findings On 3rd November 2016, key representatives from 26 different European countries were invited with a personalised link to the survey. After 14 days, 5 persons (5/26, 19.23%) had completed the survey and 2 (2/26, 7.69%) had started. Further 2 persons (2/26, 7.69%) suggested a substitute for their country, because they declared not to be qualified to answer the survey. Four weeks after the release, at the time of submission of this abstract, 10 (10/26, 38.46%) key representatives completed the survey. 5 of them (50%) had a background in research and 5 (50%) in community pharmacy. Furthermore, 5 persons had started, but had not yet completed the survey. The initially invited key representatives suggested further 25 representatives which were invited in the meantime.

Conclusion At the time of abstract submission, a satisfying response rate was achieved proving feasibility of the survey. We are looking forward to present first results from the two parts of the survey during the PCNE working conference 2017.

Portuguese pharmacists’ perceived needs of education in anticoagulation

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Background Atrial fibrillation is the most common cardiac arrhythmia globally, responsible for one third of strokes, and often resulting in death or incapacity. In recent years, therapeutic treatment options have expanded with the introduction of novel oral anti coagulants (NOACs) and subsequent expansion of their indications. However, the extent to which pharmacists have increased their knowledge and confidence in this therapeutic area remains unclear.

Purpose To identify and assess pharmacist’s knowledge gaps in the areas of anticoagulation (AC), and to compare and contrast knowledge gaps by therapeutic area; by area of practice; and by country’s provision of pharmacy services.

Method An online survey was developed by iPACT in English and subsequently translated and adapted to 19 countries, including Portugal. The survey comprised a total of 25 questions divided into 3 domains (general confidence level with advising patients on AC; perceived training needs; and training formats preferred) and was disseminated via a link in the society’s newsletter. Sub-group analysis assessed differences between confidence levels by therapeutic groups. Countries were clustered according to the literature into: advanced level (Australia, the Netherlands and Canada) and basic level service provision (Brazil, Hungary and Gulf Countries); and Portugal’s performance was compared with these 2 groups. Statistical analysis was performed using SPSS[®] version 24, focusing on bivariate analysis to compare confidence by therapeutic class and by country, and descriptive analysis of preferred forms of training.

Findings After 9 months, 181 responses were obtained in Portugal out of a total of 3324 participants worldwide. The confidence levels of pharmacists to counsel patients on vitamin K antagonists (VKA) was significantly higher than for newer non-vitamin K oral anticoagulants

PRACTISE survey-Pharmacist-led Cognitive services in Europe: first results

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Background In Europe, a change from product to services centred community pharmacy practice was reported, with a large variance in dissemination of different community pharmacy services. Cognitive services such as medication review (MR) emerged as an important topic and recently the official PCNE definition of MR was released. The aims are to map the remuneration models of different pharmacist-led cognitive services in primary care across Europe, with a special focus on MR and to update a survey by Bulajeva et al. (2014).

Purpose The project was initiated at the PCNE working symposium in Hilerød (2016) by an international project team of PCNE members from Portugal, Slovenia and Switzerland. This project team is supported by further PCNE members from The Netherlands, Denmark, Finland, and Belgium.

Method The study has a cross-sectional design with an online-survey covering two topics: Part A about 21 different pharmacist-led cognitive services (44 items) and Part B about the different types of MR (63 items). For the survey the online tool Findmind was used. To collect representative data of the current situation in Europe, at least three participants per country/region with special background (community pharmacy, policy maker, and research) and with insight in

Appendix VI– Abstract presented at the 6th working symposium of the Pharmaceutical Care Network Europe (PCNE), 2–3 February 2018, Fuengirola published in *International Journal of Clinical Pharmacy*

Int J Clin Pharm

Purpose The conSIGUE program has completed two phases to date. The aim of the first phase, conSIGUE Impact (2009–2013), was to evaluate the impact of the Medication Review with Follow-up (MRF) service on clinical, economic, and humanistic outcomes under highly controlled conditions in a cluster-randomized clinical trial. In the second phase, conSIGUE Implementation (2013–2016), the effectiveness of the implementation (based on the FISph implementation model) and its health outcomes were evaluated under routine conditions using a hybrid effectiveness–implementation design.

Method Patients in both phases were aged 65 years or older, poly-medicated (≥ 5 drugs), and chronically ill. In the conSIGUE impact phase, MRF was performed for 6 months by 250 trained community pharmacists from 178 pharmacies in six Spanish provinces (Granada, Gipuzkoa, Santa Cruz de Tenerife and Las Palmas), involving 1403 patients (intervention group, 715; control group, 688). In conSIGUE Implementation, MRF was performed for 12 months by 222 community pharmacists from 126 pharmacies in eleven Spanish provinces (A Coruña, Albacete, Ciudad Real, Córdoba, Granada, Guadalajara, Gipuzkoa, Huelva, Las Palmas, Santa Cruz de Tenerife and Valencia), involving 877 patients.

Findings In the conSIGUE Impact phase, uncontrolled health problems of the patients were reduced by 56%, visits to an emergency department by 49%, and hospital admissions by 55%; it achieved an average reduction of 0.15 drugs and increase in perceived health-related quality of life of 6.6. In the conSIGUE Implementation phase, uncontrolled health problems were reduced by 54%, visits to an emergency department by 53% and hospital admissions by 59%; it achieved an average reduction of 0.39 drugs and increase in perceived health quality of life of 6.7. A health economic study of the Impact phase showed that the service was highly cost-effective. The outcomes were very similar in both phases, although it should be taken into account that these were obtained over a 6-month period in highly controlled conditions but required 12 months to achieve under routine conditions.

Conclusion According to these results, MRF is a highly effective service. Its implementation by community pharmacies could contribute to the sustainability of the Health System and could also be useful to evaluate the reconciliation of patients after hospital discharge.

Exploring self-medication amongst pharmacy patients in Kosovo

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Background Patient self-medication commonly affects medication adherence and overall therapeutic outcomes. Patient self-medication from community pharmacies in Kosovo is presumed to be common, however this issue has not been previously explored.

Purpose Explore self-medication in Kosovo pharmacy patients, including conditions, medications and potential implications.

Method This was a quantitative perspective study in which data was collected using a self-administered survey of pharmacists. This survey was distributed directly to pharmacies and pharmacists had the option of also self-administering the survey online. The survey included statements on Likert scale and its design was based on a literature review and also included open and closed ended questions. Data analysis was performed using the SPSS Vs 20 where initially descriptive analysis was performed followed by parametric and non-parametric tests to check variable associations.

Findings A total of 102 pharmacists were surveyed. Findings suggested that pharmacy patients in Kosovo commonly self-medicate with over 54% of surveyed pharmacists indicating that their patients

self-medicate without prescription on daily basis. Out of medication groups requiring prescriptions in Kosovo, pharmacists reported that their request to supply medication without prescriptions is more commonly for contraceptives and antibiotics (mean agreement values on Likert scale: 4 and 3.8 respectively). Pharmacists indicated that they more commonly supply medicines without prescriptions for urinary tract and respiratory infections followed by insomnia (mean agreement values on Likert scale: 3.8, 3.5 and 3.2 respectively). According to majority of pharmacists (74%), patients in the age group between 31 and 45 years of age were more strongly associated with self-medicating ($p < 0.01$). Previous disease diagnosis and parents self-medicating their kids were most common situations where patients require medicines without prescription (mean values on Likert scale: 4.09 and 3.57 respectively). This study also evaluated advantages, disadvantages and implications of self-medication for Kosovan patients.

Conclusion This study identified a high rate of self-medication in patients frequenting pharmacies in Kosovo. Findings highlight the need for a more proactive role that Kosovan pharmacists need to assume with the view of raising public awareness of self-medication implications.

Adaptation of e-consensus technique on PRACTISE Study—Pharmacist-led Cognitive services in Europe

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Background Different methodologies are used to achieve consensus on a subject. These can include the Delphi technique, the Expert panel, and more recent adaptations, both in content and in method for reaching respondents. During the PRACTISE-study we have sought 3 respondents per country/region evaluate the implementation of various pharmacist-led cognitive services.

Purpose The aim of this study is to describe the adapted consensus method used to achieve country/region consensus within PRACTISE-survey respondents.

Method This process involved two rounds: in the first round, the previously developed questionnaire was sent to selected participants (aiming at three per country/region). To achieve consensus within the country/region we classified them into three groups according to the number of respondents included in round one: group A: countries/regions with 1 respondent; group B: countries/regions with 2 respondents; group C: countries/regions with 3 respondents. During the second round, different documents and procedures for validation purposes were used. In group A, the document was sent to a fourth person from the same country/region, who acted as a validator of the responses obtained by the sole responder obtained. In groups B and C, a consensus document was developed and sent to the same participants, informing them of previous responses and asking them to rethink their answers aiming for consensus.

Findings The first round lasted from November 2016 to March 2017 obtaining responses from 34 countries/regions (2.5 respondents per country/region). The first analysis was undertaken by two independent PRACTISE team members aiming to prepare the consensus documents (one per country/region). Round two was initiated in early July, when documents were sent to the three groups. A response rate of 91.1% ($n = 34$) was obtained in round two. Group A included 7 countries/regions, and we were able to find validators to 5 of them (response rate = 71.4%). Group B comprised 12 countries/regions